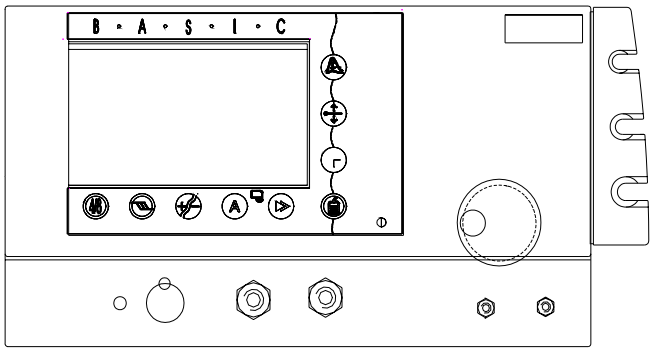
BASIC



USER'S MANUAL

01 274 H

This document contains information on the **BASIC** manufactured by ATYS Sarl. Information in this document is subject to change without notice and does not represent a commitment on the part of ATYS Sarl. ATYS Sarl does not assume liability for damages that may occur as a result of the use of the information in this manual. No part of this manual may be reproduced or transmitted in any form for any purpose other than the use of the purchaser of **BASIC** system.

01 274 Rev. H
Reference:
BASIC USER'S MANUAL

July 15th, 2005

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CAUTION: In USA, Federal law restricts this device to use by or on the order of a physician.

CAUTION: The **BASIC** is not intended for fetal monitoring or fetal use.

CAUTION: The air plethysmography and the systolic pressure measurement modules of the **BASIC** are not intended for neonatal applications.

CAUTION: The **BASIC** is not intended for ophthalmic application.

CAUTION: The **BASIC** or a probe must not be used if damaged.

CAUTION: The **BASIC** must not be used out of the specified environment.

CAUTION: The operator should limit the length of the Doppler tests to the time required for diagnostic purposes to minimize his/her exposure to ultrasound and as well the patient's.

CAUTION: To prevent fire and electrical hazards, keep the **BASIC** out of rain, water and humidity.

CAUTION: The **BASIC** is not intended to be used on non intact skin

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1. FOREWORD

This user's manual is for three models of **BASIC**:

- **BASIC 1**: 4 and 8 MHz Doppler.
- **BASIC 2**: 4 and 8 MHz Doppler fitted with a two-channel photo-plethysmograph.
- **BASIC 3**: 4 and 8 MHz Doppler fitted with a two channel photo-plethysmograph and a one channel pneumo-plethysmograph.

MODULE	BASIC 1	BASIC 2	BASIC 3
Doppler 4 and 8 MHz	yes	yes	yes
Photo-plethysmography two channels	no	yes	yes
Pneumo-plethysmography	no	no	yes

EXAMINATION	BASIC 1	BASIC 2	BASIC 3
Velocity measurement	yes	yes	yes
Digital test (Photo-plethysmography)	no	yes	yes
Venous reflux test	no	yes	yes
Pulse volume recording	no	no	yes
Ankle Brachial index	no	no	yes
Pressure in digit and limb	no	no	yes
Systolic pressure examination	no	no	yes

1.1. Hardware components of the BASIC

The **BASIC** consists of the following components:

- Doppler and plethysmography processing unit
- Remote control
- Integrated thermal printer
- Integrated LCD
- Footswitch
- 4 and 8 MHz probes
- Arterial and venous photo sensors (**BASIC 2** and **BASIC 3**)
- Pressure cuffs (**BASIC 3**)

The cuffs are the only **BASIC** accessories. Their specifications are reported in § 20.

1.2. Indications for use

When a patient's history and symptoms indicate a possible vascular problem, the **BASIC** can be used by a trained medical personnel to:

- Confirm the indication,
- Locate the site of the vascular irregularity,
- Determine the severity of the problem.

In each mode, the following exams can be performed:

- **Doppler mode**: use to evaluate blood flow in the arteries and veins and as a stethoscope to examine systolic pressures at different locations.
  You can perform a general Doppler procedure, a Doppler venous exam and take systolic pressure.

The functions of the transducers are reported in the table below.

8 MHz CW Transducer	**4 MHz CW Transducer**
Digital Artery Evaluation Vessels closer to the skin surface Smaller patients	Extracranial Carotid Evaluation Vessels deeper in the body Larger patients Venous evaluation

- **Photo-plethysmography mode (PPG)**: used to evaluate capillary blood flow in tissues. You can used PPG in the arterial or venous mode. The arterial mode is used to assess the arterial blood supply to a specific location.
  You can also record systolic blood pressure in the extremities while using the PPG arterial mode.
  The venous mode is used to assess valvular insufficiency by performing a Venous Reflux Test.

- **Pneumo-plethysmography mode**: used to record changes in blood volume in the arms, legs, fingers and toes. You can perform an exam in the pneumo-plethysmography arterial mode. The arterial mode allows to assess arterial blood supply to a specific location on a patient's body.

Comment: a Doppler probe or an arterial photoplethysmography sensor and a pressure cuff are required to perform systolic pressure examination.
A pressure cuff is placed on the leg, arm or digit under examination. The Doppler probe or the arterial photoplethysmography sensor is used to locate an artery distal to the cuff.
The cuff is inflated to stop blood flow. Then as the cuff deflates, the Doppler probe or the arterial photoplethysmography sensor detects the returning blood flow.
The systolic blood pressure is measured at different levels in the upper and lower extremities to determine the pressure differences or ratios in the segments between two cuff locations. Large pressure differences indicate arterial disease.
The important data are not the absolute value of the pressures but the pressure differences or ratios.

The **BASIC** performs the following types of automatic tests:

- ABI (Anckle/Brachial Index) test with Doppler: screens a patient for arterial disease in the legs by using Doppler ultrasound.
- ABI (Anckle/Brachial Index) test with photo-plethysmography: screens a patient for arterial disease in the legs by using photo-plethysmography.
- Penile pressure test.
- Segmental test with Doppler: isolates and characterizes the severity of arterial disease in the legs by using Doppler ultrasound.
- Segmental test with photo-plethysmography: isolates and characterizes the severity of arterial disease in the legs by using photo-plethysmography.
- Pulse volume recording with photo or pneumo plethysmography.
- Digital test: evaluates the arterial blood flow in the hands or feet.
- Venous reflux test: provides an indication of incompetent valves in the superficial and deep veins of the legs.
- Direct Doppler carotid test: evaluates possible stenosis of the common carotid, internal carotid and external carotid arteries.

1.3. Contraindications

The **BASIC** is not intended for:

- Fetal monitoring or fetal use.
- Fetal imaging & others (Abdominal; intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic).
- Ophthalmic application.
- Home use.

The air plethysmography and the systolic pressure measurement modules of the **BASIC** are not intended for neonatal applications.

Do not use the probes, the sensors and the cuffs on skin surfaces with recent wounds/operative cuts.
Never use a cuff with patient suffering from swollen lymph glands and/or lymph edema.
Always use the correct cuffs for the different sites in order to minimize the patient's inconvenience.
Use all cleaning and disinfection procedures applicable to your institution.

1.4. Precautions and warnings

Ultrasonic waves penetrate deep into the biological tissue. The effects of ultrasound on living tissue and organisms have yet to be fully researched, although many years of use in clinical applications in a wide variety of areas have shown it to be harmless.
Ultrasound should be employed with care and used only in situations where the results outweight the risks. Patients should not be subjected to unnecessarily high doses.

- In USA, federal law restricts this device to use by or on the order of a physician with the operator presence at all times while the patient is connected to the system.
- Do not leave the unit on line with the Doppler probes on the patient if it is not necessary for the appropriate diagnostic procedure.

1.5. Customer responsibility

The **BASIC** performs properly only when operated and maintained as specified in this manual and the **BASIC** service manual. It is the responsibility of the customer to use the **BASIC** in accordance with the instruction manual, the warnings and the labels.

If the product is found defective, it should not be used. The system should not be used if any parts are missing or are damaged. Parts that are visibly broken, worn out, warped or contaminated must be replaced immediately with new parts supplied by ATYS. No components should be replaced with parts from any other manufacturer. If the customer suspects a part may be defective, it is the customer's responsibility to contact ATYS.

1.6. Patients and examiners safety

To prevent electrical shock hazards, do not remove cover. For service, contact a qualified service representative.

Switch off the power to the system before attempting any service or maintenance activity related to cabling or connections.

Have a service engineer check the integrity of the system ground and leakage current every year.

To prevent fire and electrical hazards, keep the **BASIC** out of rain, water and humidity. If the system does come in contact with water or any liquid, shut the system down and disconnect the system from the power cable and contact your ATYS service representative.

The **BASIC** must not be operated in presence of flammable anesthetics.

The **BASIC** must not be operated or stored outside the specified environment conditions.

Inspect the power cable for signs of fraying or other damage before each setting. Do not operate the system if the power plug or cord is damaged.

In 120V operation, use a 125V 10A and UL power cable with ground and place the voltage selector on 120V.
In 240V operation, use a 250V 5A and IEC power cable with ground and place the voltage selector on 240V.

In USA, only FDA cleared blood pressure cuffs must be connected to the **BASIC**. The characteristics of the cuffs compatible with the **BASIC** are reported in § 20.

1.7. Serial number

Write here the serial number of your **BASIC**. It is on the backside on the identification label.

11 _____

1.8. Validity of the calculated indices

The displayed values of the indices are available only under certain conditions of good quality measurements. These conditions can be identified in the curve on the screen as on the printing. For further details, read section "**OPERATION**".

1.9. Factors influencing ultrasound power output

With continuous wave ultrasound, a transducer sends continuously ultrasound into tissue and a second transducer receives continuously the reflected back ultrasound wave.
Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. This effect is very low with peripheral Doppler because the ultrasonic power is very low and is constant. It is not controlled by the user.
Atys has always endeavoured to use as low an ultrasonic power output for our products as is practical. All power levels are significantly below those currently established by the FDA as limits above which specific review is necessary.

1.10. Adverse effects

Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound.
However, exposure should always be limited As Low As Reasonably Achievable (ALARA principle).

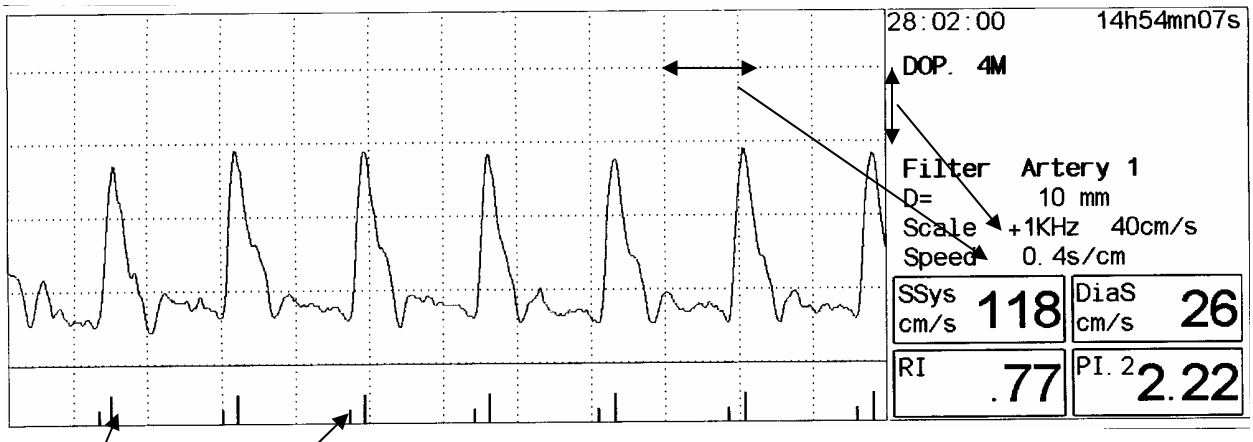
2. SYMBOLS

2.1. Symbols used on the keyboard

Icons used on the **BASIC** and in the user's manual.

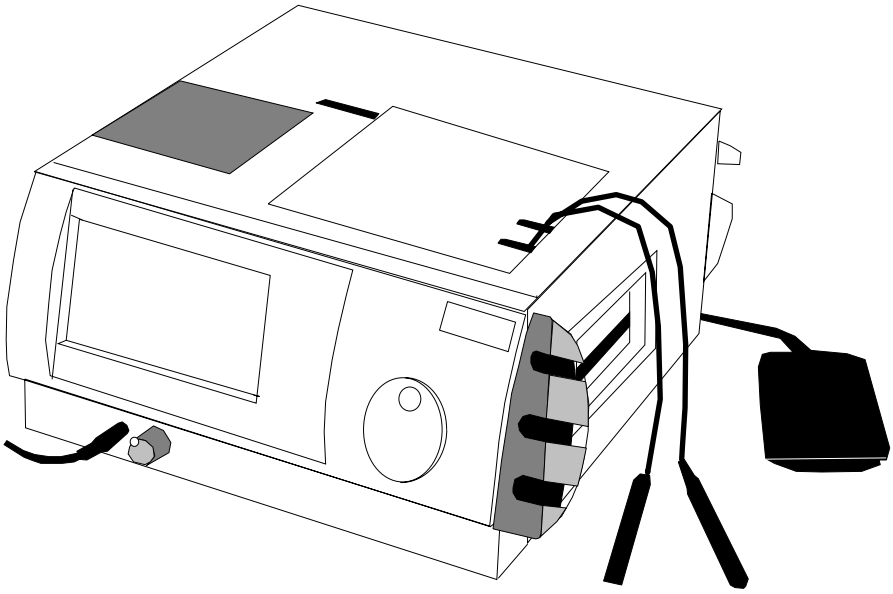
Icons	Name of the key
	Probe
	Sign
	Filter
	Zero line
	Operating mode
	Null
	Sweep
	Amplitude
	Pedal

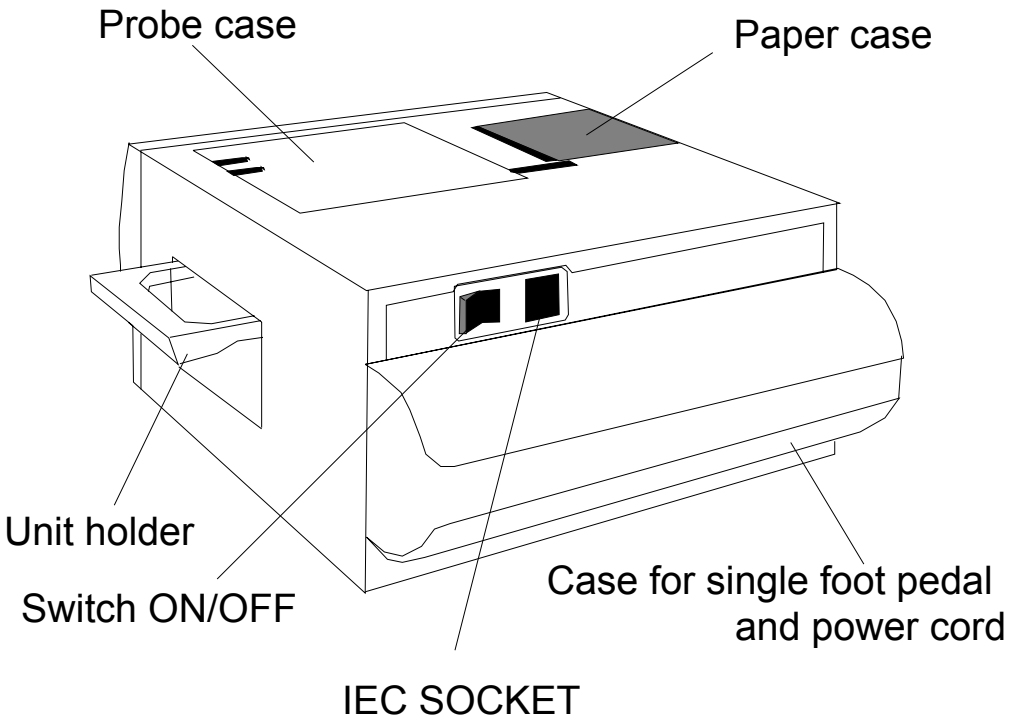
2.2. Symbols used on printing

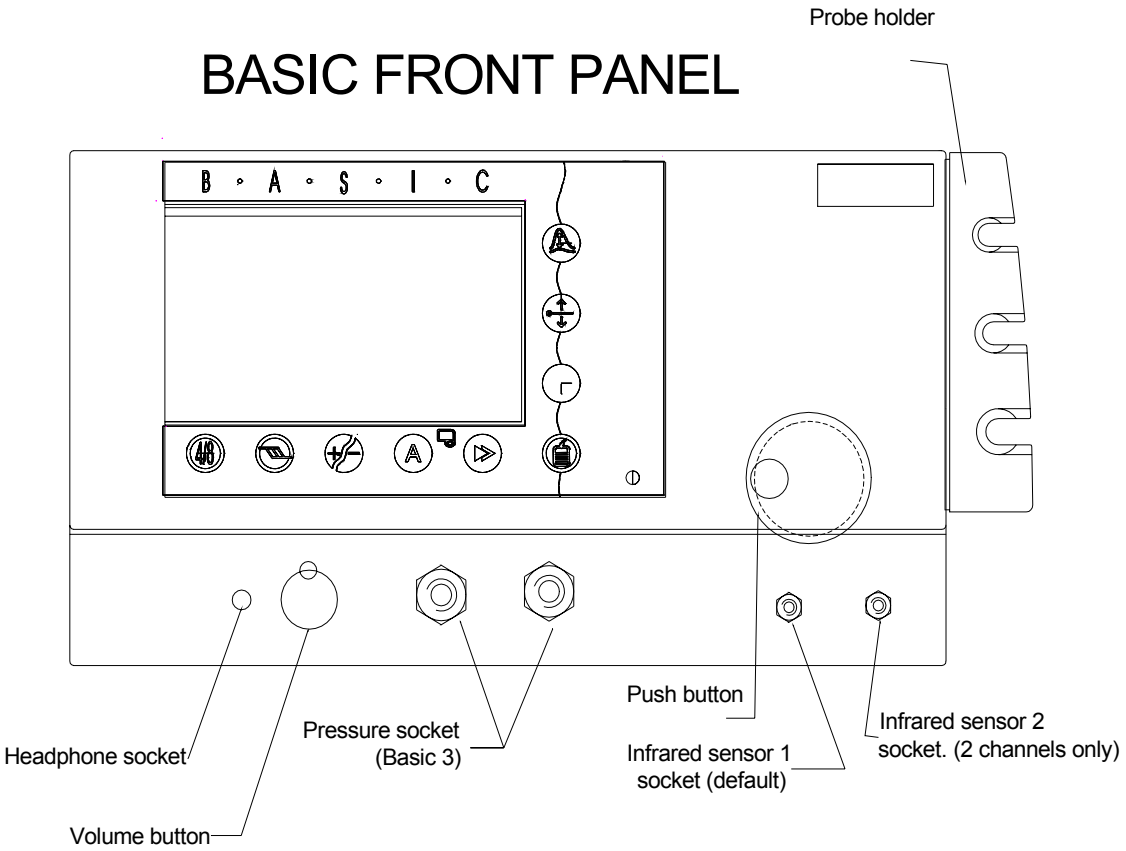


3. SETTING

3.1. Console

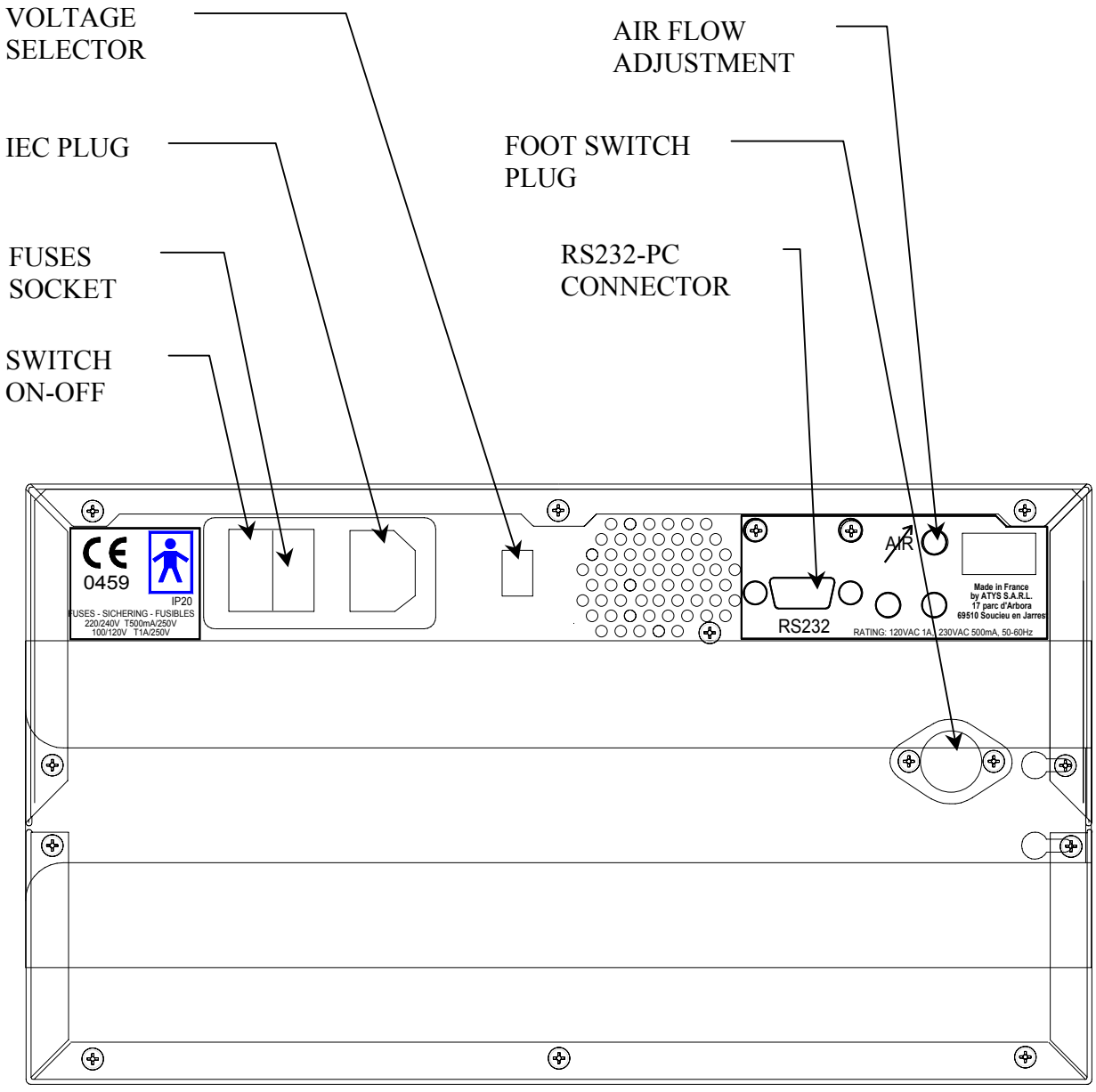






Comment: In the following, the push button is renamed QuickButton.

REAR PANEL


VOLTAGE SELECTOR
AIR FLOW ADJUSTMENT
IEC PLUG
FOOT SWITCH PLUG
FUSES SOCKET
RS232-PC CONNECTOR
SWITCH ON-OFF
0459
IP20
FUSES - SICHERING - FUSIBLES
220/240V T500mA/250V
100/120V T1A/250V
AIR
RS232
Made in France
by ATYS S.A.R.L.
17 parc d'Arbora
69510 Soucieu en Jarres
RATING: 120VAC 1A, 230VAC 500mA, 50-60Hz

3.2. Mains connection

At the delivery, the power cord is put in the rear case.
The mains connection is operated by an IEC type cable delivered with the **BASIC** (IEC 5A in 220V, UL 10A in 110V). This cable can be taken off the **BASIC**. The switch beside the plug allows to switch on and to switch off the **BASIC**.
The switching on is indicated by the backlightning of the display.
The power cable can be placed in its transportation case and remain connected to **BASIC**.

Caution: for safety, it is important to check the proper state of the power cable before each setting.

3.3. Probes and sensors

4 et 8 MHz
Doppler probes

Venous photo sensors

Arterial photo sensors

3.3.1. Probes

At the delivery, the Doppler probes are connected in the upper case. They are locked by screwing.
A single push on the cover of the probe case is enough to lock or unlock it.
Take the probes out of their case and put them on the probe holder.
Before locking the cover of the probe case, check that the cables go out of the case through the holes provided in the cover.

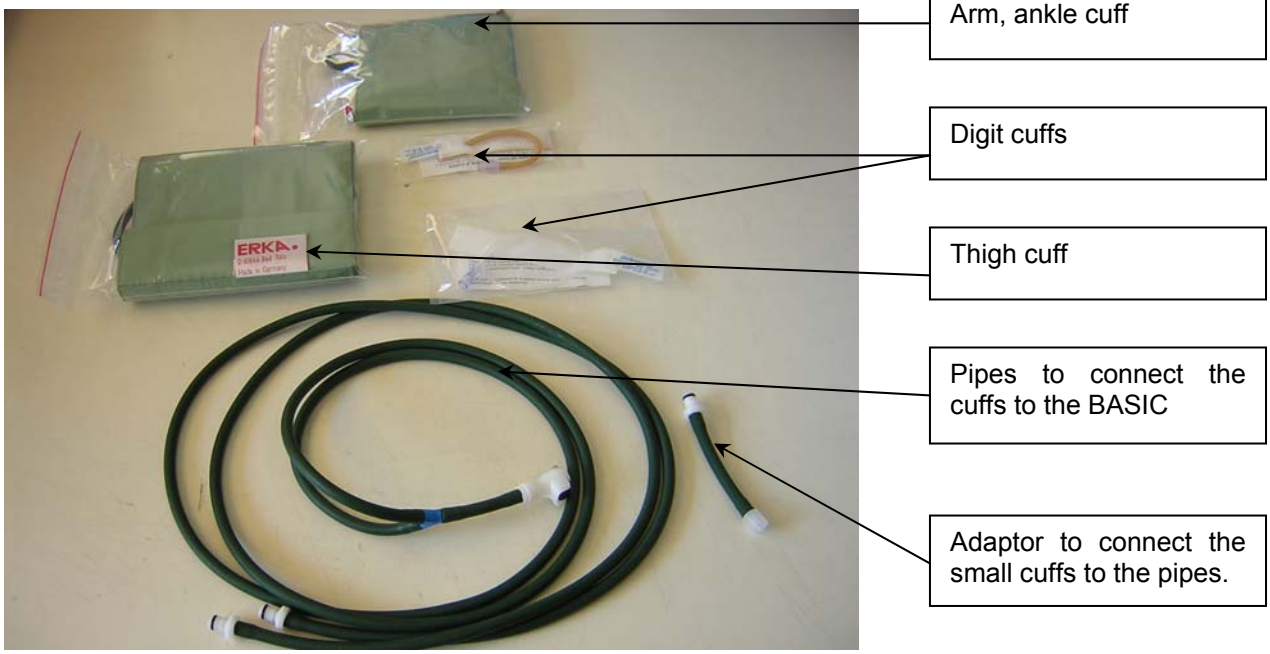
3.3.2. Infrared sensors

Connect the two infrared sensors in the two connectors located on the front panel.
In the one channel photo-plethysmography exam, only the left-hand side connector is active.

In the two channel photo-plethysmography exam:

- The right hand side connector is related to the patient's right side,
- The left-hand side connector is related to the patient's left side.

3.3.3. Cuffs


Arm, ankle cuff
Digit cuffs
Thigh cuff
Pipes to connect the cuffs to the BASIC
Adaptor to connect the small cuffs to the pipes.
ERKA

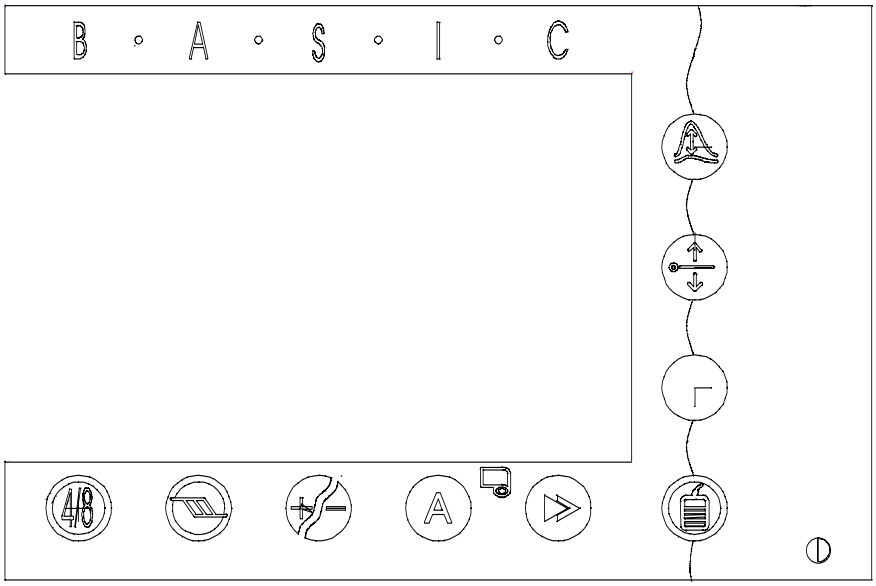
3.4. Screen

The contrast of the display is adjusted by means of the knob located below the lower side of the front panel and indicated by this icon: ◑.

Caution: the screen must not be exposed at the sun or heat.

3.5. Keyboard

Control keyboard and display



4/8 **Probe**: this key allows to switch from 4 MHz to 8 MHz or from 8 MHz to 4 MHz.

Amplitude: Press this key to adjust the amplitude. This key allows to select successively the different values.
The amplitude must be well adjusted in order to get accurate results:

- The waveform must not be truncated.
- The waveform must not be too small with regards to the available space on the screen. The waveform must take full advantage of the available space.

Filter:

- **In Doppler mode**: Press this key to select the filter. This key allows to select successively the filters Artery 1, Artery 2, Vein and Average and then to return to Artery 1. The selected value is written on the display as Artery 1, Artery 2, Vein and Average respectively.
  This filter allows to smooth the waveforms.
- **In plethysmography mode**: Press this key to select the examination type, arterial or venous. The selected value is written on the display as Artery or Vein.

Sweep: Press this key to select the sweep speed. This key allows to select successively the speeds 5, 1.6, 0.8, 0.4 then to return to the value 5. These values are indicated in s/cm or s/div

+/− **Flow direction**: This key is used only in Doppler mode.
This key is the flow direction key; press this key to switch from "+" to "-" or from "-" to "+".
+ indicates that the blood flow displayed above the zero line runs toward the probe.
- indicates that the blood flow displayed above the zero line runs away from the probe.
Normally the flow towards the probe is displayed above the zero line and the flow away from the probe is displayed below the zero-line.
CAUTION: The indices are properly calculated only if the blood velocity is displayed above the zero line.

Zero line: Press this key to adjust the zero line location. This key allows to move the zero line from the first division that corresponds to the lower edge of the frame up to the third division;

there are three possible locations of the zero line. This adjustment of the zero line allows to take advantage completely of the amplitude of the signal.

A **Printer operating mode**: Press this key to select the "**continuous**", "**immediate**" or "**automatic**" mode. This key allows to switch from one mode to the other.
The selected operating mode is indicated on the display with the following symbols:

- Continuous: CONT
- Immediate: IMDT
- Automatic: AUTO

In "**continuous**" mode, the **BASIC** operates as a conventional paper recorder. One push on the "**Pedal**" key allows to start the recorder, a second push allows to write on the paper the adjustment parameters and to stop the paper recorder.

In "**immediate"** mode, a push on the "**Pedal**" key allows to freeze the display.
If the frozen curve is not satisfying, a push on the "**Null**" key allows to resume the examination without printing.
A second push on the "**Peda**l" key allows to print the frozen curve.
Once the printing is over, the display is unfrozen and the examination can be resumed.

The "**automatic**" mode is similar to the "**immediate**" mode but once the printing is over, the display remains frozen. To resume the examination, press the "**Null**" key.

Pedal: This key is equivalent to the foot pedal.

- This key allows to freeze the acquisition.
- This key allows to print the display.
- This key has a validation function during specific examinations.

Null:
This key is equivalent to the right switch of the double switch foot pedal (the double switch foot pedal is an option).
This key allows to exit menus.
This key has also a START/EXIT function during specific examination:

- Venous reflux test.
- Pressure measurement.
- Pulse volume recording (inflate the measure cuff).
- Reset to zero in photo-plethysmography venous mode.

When the curve is frozen, press this key to resume the examination without having to print the frozen curve.

3.6. Paper and printing

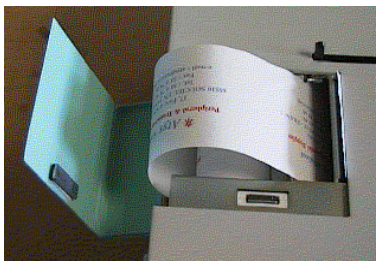
3.6.1. Local printing

Paper type
The printing paper is thermal paper especially designed for ATYS to obtain the best result and the longest life of the printer. It is not compatible with the types of thermal paper used with fax for instance (the point of temperature is higher).

Unexpected stop of printing
In case of lack of paper or if the paper insertion lever is up, the printing stops till the correction of the mistake. A red line on the paper indicates the near end of the paper.

Changing the paper
Open the cover of the paper case and raise the lever to free the printing head.
Enter the paper through the lower opening of the printing head; the upper opening is dedicated to the output of the paper.
The paper roll is placed in its case so that the paper can go out horizontally towards the insertion slot.
The direction of the paper enrolling must be respected to place the thermal sensitive side properly (that is downwards at the insertion, visible when ejected).
Put down the lever.

At the end of printing, the paper is ejected in order to place the line to cut in front of the cutter. At the start of printing, the paper is swallowed again in order to begin the printing on the edge of the paper. In this way, the printings follow one another with no blank between them.



3.7. Sound (Doppler only)

A button on the front side controls the sound volume. The balance and the tonality adjustments are operated in factory.
The loudspeakers are on the lateral sides of the **BASIC**.

Note 1: be cautious not to introduce any object or liquid into the sound outputs at the risk of damaging the equipment.
Note 2: to obtain a proper sound quality, be cautious not to obstruct these outputs.

3.8. Foot switch

At the delivery, the single foot switch is put in the rear case.
A single or double (option) foot switch allows remote control.
The function of the foot switch is also available on the control keyboard. The equipment then can be used without foot switch.
The single foot switch is equivalent to the "**Pedal**" key.
For the double switch pedal:

- The left switch is equivalent to the "**Pedal**" key.
- The right switch is equivalent to the "**Null**" key.

Plugging
The foot switch, if needed, must be connected to the DIN socket located on the rear panel.

The single foot switch can be placed in its transportation case, next to the power cable, where it can remain connected to the **BASIC**.

3.9. Headphones

To connect your headphones, the following operations are to be performed otherwise you may damage your headphones and **BASIC**:
CAUTION: Use only stereo earphones; other earphones may damage the **BASIC**.

- Switch off the **BASIC**.
- Cut off the sound from the loudspeakers (turn the volume control button fully counter clockwise).
- Connect your headphones on the front panel.
- Switch on the **BASIC**.

3.10. Transportation

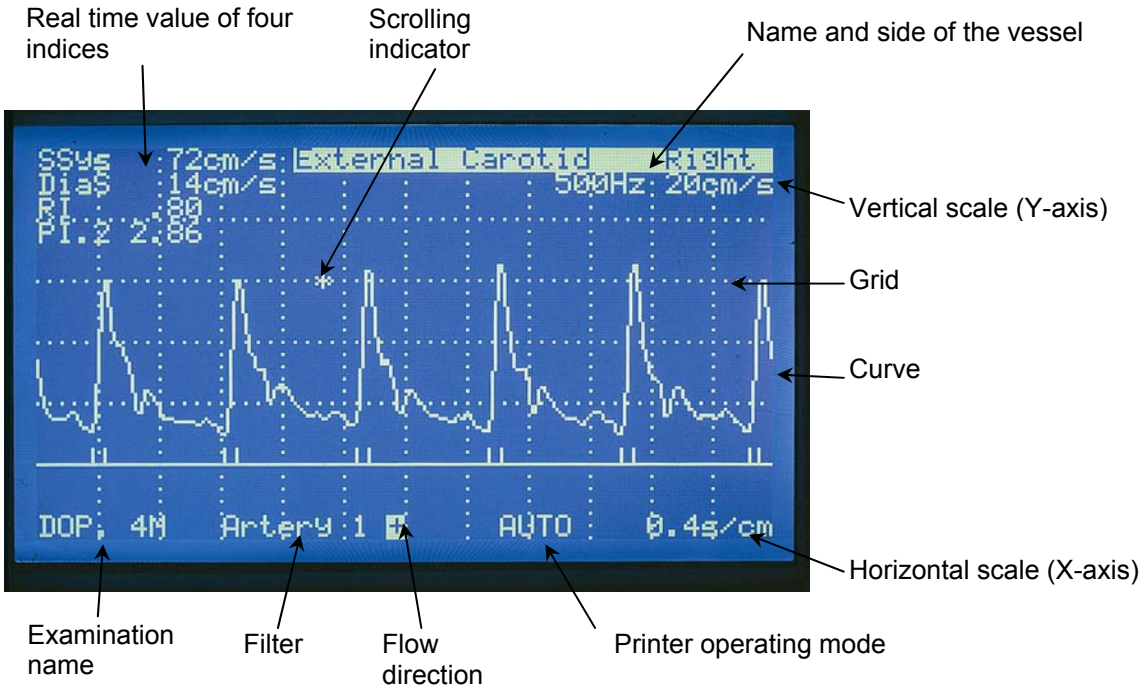
For transport:

- Put the Doppler probes in their case.
- Remove the infrared sensor and the cuff.
- Take out the lateral handle.
- Check that the cover of the paper roll case is well locked and put the **BASIC** on its lateral feet.
- Put the foot pedal and the power cord in the rear case. For the transport the foot pedal and the power cord can remain connected to the **BASIC**.

4. OPERATION

4.1. Objects on the acquisition screen

The following screen represents the acquisition screen.



4.1.1. Curve

This object represents the analysis of the signal from the probe or the sensor.
The curve is modified during the signal acquisition with a frequency of 200 times per second.
The curve is drawn from the signal processing. It represents the instantaneous values used to calculate the indices.

4.1.2. Grid

A grid is displayed; it allows an estimation of the values of the points of the curve and time.
The units of the grid are reported on the screen.

4.1.3. Vertical unit

4.1.3.1. Doppler

The blood flow velocity is expressed:

- in Hz, which indicates directly the frequency deduced from the analysis.
- in cm/s, taking into account a constant angle between the probe and the blood flow.

The scale unit used in Doppler physics is Hz. However, the user frequently needs to know the velocity value as a clinical measure. The measure in Hz is more precise but depends on the probe frequency.
The velocity scale is displayed beside the "**Amplitude**" key.

4.1.3.2. Photo-plethysmography

The gain is displayed beside the "**Amplitude**" key.

4.1.3.3. Pneumo-plethysmography

The scale is expressed in mmHg/division. It is displayed beside the "**Amplitude**" key.

4.1.4. Horizontal unit (Time scale)

The time scale depends on the sweep speed (or paper unrolling speed). The sweep speed is the speed at which the curve moves across the screen.
The time scale, expressed in s/division (or in s/cm) (one division on the paper printout is equal to 1 cm), is equivalent to the number of seconds per division.
The time scale is displayed above the "**sweep**" key.

4.1.5. Examination

The name of the selected examination type is displayed on the screen above the "**Probe**" key

The following data can be displayed:

- **Dop. 4 M**: 4 MHz Doppler.
- **Dop. 8 M**: 8 MHz Doppler.
- **PPG Ph2**: Two channel Photo-Plethysmography.
- **PVR Pn1**: Pulse Volume Recording, one channel Pneumo-Plethysmography.
- **PPG Ph1**: One channel Photo-Plethysmography.
- **V.R.T.**: Venous Reflux Test.

4.1.6. Filter

The name of the selected filter is displayed on the screen above the "**Filter**" key. The following data can be displayed:

- In Doppler mode:
  - Artery 1.
  - Artery 2.
  - Vein.
  - Average.

- In Plethysmography (PPG ph2, PPG pn1, PPG ph1):
  - Artery: this filter is selected for arterial examination.
  - Vein: this filter is selected for venous examination.

4.1.7. Flow direction

In Doppler mode only, the sign "**+**" or "**-**" is displayed on the screen above the "**Sign**" key.
By convention, the velocity is positive if the blood flows towards the probe and the velocity is negative if the blood flows away from the probe.

4.1.8. Printer operating mode

The name of the selected printer operating mode is displayed above the "**Operating mode**" key.
The following data can be displayed (see § 3.5):

- **AUTO**: Automatic mode.
- **IMDT**: Immediate mode.
- **CONT**: Continuous mode.

4.1.9. Message

A message can be displayed on the bottom or the right hand corner of screen. This message let you know what must be done.

4.1.10. Indices

The device displays the real time value of up to four indices. The indices are displayed on the upper left-hand corner of the screen.
Composition
Each index is composed by:

- four characters name,
- four characters unit,
- value.

Calculation
The indices are calculated:
- In real time, every second.
- In delayed time, during the scrolling, on the last cycle visible on the screen.

The value of the index is displayed only if it is correct.
When it is not correct, the value is replaced by "**---**".

If the waveform is truncated, the indices are likely to be underestimated.
If the waveform is too small with regards to the whole display, the indices are likely not to be calculated.

Choice
The index type is chosen by the user among a listing with the **configuration menu**.
The indices are selected for each probe or sensor.
The available indices are presented in § 13.4.3 "**CONFIGURATION**, section "**Index configuration**".

4.1.11.Clock

The clock indicates the present time.
This value can be modified by the user with the **configuration menu**.
The time is stored thanks to a battery.

4.1.12.Cine-loop indicator

The **BASIC** is fitted with a buffer. The buffer can store up to 1 min duration of an examination.
The indicator is one or several stars between two brackets [**].
The stars indicate the location of the displayed window in the entire recording.

4.1.13.Side indication

It is automatically displayed for the following examinations:
- PPG Ph2 (two channel Photo-Plethysmography).
- VRT Venous Reflux Test.

For these two examinations, the side indication is displayed on the left-hand side of screen as follows:
- Right.
- Left.

The right side signal is displayed above "Right".
The left side signal is displayed below "Left".
The right side signal comes from the right hand side sensor; it is connected on the right connector (closest to the lower right hand corner of the machine).
The left side signal comes from the left-hand side sensor; it is connected to the left-hand side connector.

For the other tests, the side may be input by the user. In this case, it is displayed on the upper right hand corner of the screen.

4.1.14.Name

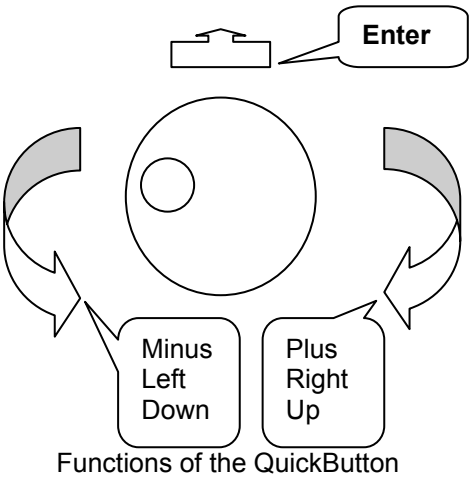
The name of the vessel may be input by the user. It is displayed on the upper right hand corner of the screen (see § 13.2).

4.2. Adjustments and controls

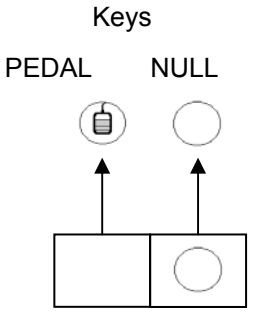
The general controls are done by the "**Pedal**" and the "**Null**" keys.

Use the QuickButton to display the **configuration menu** and to select item from the menu.
You can press the QuickButton and turn it in both directions.
When you turn the QuickButton counterclockwise, the cursor moves down in the menu.
When you turn the QuickButton clockwise, the cursor moves up in the menu.

From the acquisition screen, press the QuickButton to display the **configuration menu** (see § 13).
To select an item from a menu, move the cursor on the item and press the QuickButton.
Once the item is selected and adjusted, press again the QuickButton to validate your choice.



Functions of the QuickButton



Double switch foot pedal

CAUTIOUS: in the user's manual the following notation will be used

- Press "**Enter**"**:** for press the QuickButton: validation of the selection
- "**-**": for turn "**counterclockwise**" the QuickButton: moving down the cursor or changing the value of a field
- "**+**": for turn "**clockwise**" the QuickButton: moving up the cursor or changing the value of a field

In the **configuration menus**, press "**Enter**" before and after the modification of a field with "**+**" and "**-**".

During acquisition, "**+**" and "**-**" allow to change the vessel name displayed on the screen.

When the acquisition is frozen, "**+**" and "**-**" allow to display the buffer or to move a cursor in the acquisition screen.

5. DOPPLER EXAMINATION

Use the Doppler mode to assess a patient's vascular health. With this modality you can listen to the arterial or venous blood at various locations on a patient's limb and view the corresponding waveforms.
You can also obtain systolic pressures at a number of different locations on arms, legs and digits.

Use the 4 MHz probe on larger patients or when examining blood vessels that run deeper in the body. The lower frequency 4 MHz ultrasound waves penetrate deeper into the body.

Use the 8 MHz Doppler probe on smaller patients or when examining blood vessels that run closer to the surface. The higher 8 MHz ultrasound waves do not penetrate deeper into the body.

The list below may help you to choose the appropriate probe for the artery you are examining.

4 MHz probe	8 MHz
Common femoralartery	Posterior tibial artery
Superficial femoral artery	Dorsalis pedis artery
Popliteal artery	Peronal artery
Subclavian artery	Brachial artery
	Radial artery
	Ulnar artery

The Doppler probe emits ultrasound waves that hit the blood cells flowing through a vessel. These ultrasound waves bounce off the blood cells and return to the probe.

The reflected ultrasound waves change in frequency proportional to the velocity of the blood flow. This frequency change is known as the Doppler shift.

$$\Delta f = \frac{2 fe V \cos\theta}{C}$$

Where:
Δf is the frequency change that occurs when the ultrasound waves reflect off moving blood cells.
fe is the emission frequency. fe is equal to 4 or 8 MHz.
V is the velocity of the moving blood cells.
θ is the angle of the ultrasound beam to the blood flow direction.
C is the ultrasound velocity in the tissue.

The **BASIC** records the frequency shifts and calculates the velocity.
The loud speakers allow you to listen to these frequency shifts.
The various flow velocities are averaged and displayed as a single continuous waveform. As the average velocity changes, the waveform height changes proportionally.

Two important parameters affect the audible signal: frequency and strength:

- The frequency pitch depends on the velocity of the moving blood cells (the faster the cells move the higher the frequency shift.
- The volume (loudness) of a given frequency depends on how many blood cells are moving at a given velocity.

5.1. Start of the acquisition

Prepare the patient for the Doppler examination. Position him/her comfortably on the examining table. You should have access to the blood vessel you are examining. Apply a generous amount of conducting gel to the location.

For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25°C. The patient must remain relaxed throughout the exam. Remind the patient to remain still and to refrain from talking.

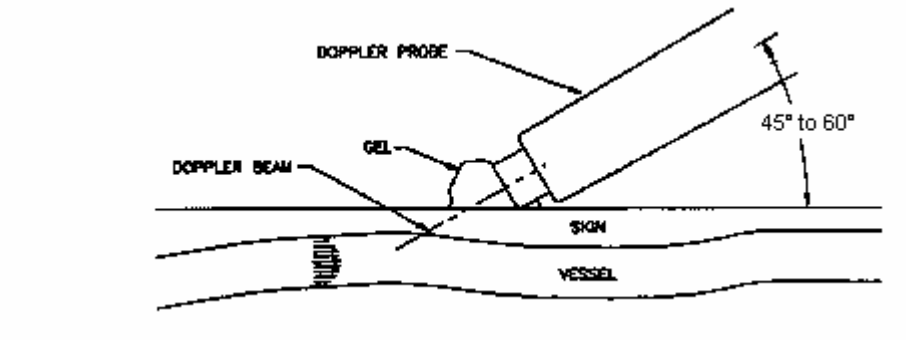
Select Doppler examination from **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **DOP. 4M** or **DOP. 8M**. **DOP. 4M** means 4 MHz Doppler. **DOP. 8M** means Doppler 8 MHz.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.
  On the acquisition screen, you can switch from the 4 MHz probe to the 8 MHz probe by pressing the following key: 4/8.

With the Doppler probe, locate the blood vessel that you want to examine. You may have to experiment with the probe until you find the best signal.

Be sure to hold the probe at a 45° to 60° angle. The probe angle is very important in obtaining a good waveform. In the Doppler shift equation, the change in frequency is proportional to the incident angle.

Do not press too hard with the probe. Pushing too hard can occlude the vessel. Use a firm but gentle touch.



The audible and the visual Doppler signals provide complementary information and both are important to your analysis. Do not rely on just one of theses results in your screening procedure.

At any time, if the screen is frozen, pressing the "**Null**" key can start the acquisition again.

CAUTION: During the acquisition with **BASIC 3**, pressing "**Null**" allows to enter the pressure measurement mode. With **BASIC 1** and **BASIC 2**, If you press "**Null**" during the acquisition the pressure measurement screen is displayed but the pressure measurement is not active. So press the "**Null**" again to go back to your acquisition window.

5.2. Adjustment

During the acquisition, the user performs the following adjustments:

- Probe selection (4 or 8 MHz).
- Sound volume adjustment.
- Amplitude adjustment. The waveform must not be truncated nor to small.
- Sweep speed adjustment. The advised value is **0.4s/cm**.
- Zero line adjustment.
- Sign adjustment. The waveform must be above the zero line.
- Filter selection. The standard filter in arterial mode is **Artery 1**.
- Selection of the vessel name or side (turning the QuickButton if the screen is not frozen or with the **"Select vessel"** menu; you can reach this menu by pressing the QuickButton).
- The printer operating mode. The Immediate mode (IMDT) is advised.

Generally, the different adjustments are stored; it is not necessary to modify them.

5.3. Acquisition quality

The acquisition quality can be judged according to the following criteria:

- The number and the location (one per cycle) of the systole and diastole markers have to be correct.
- The displayed heart rate is a good indicator, easy to check. It must be steady (the discrepancies between two successive cycles must not be greater than 10%) and coherent with the patient heart rate.

5.4. Validation

Display freezing

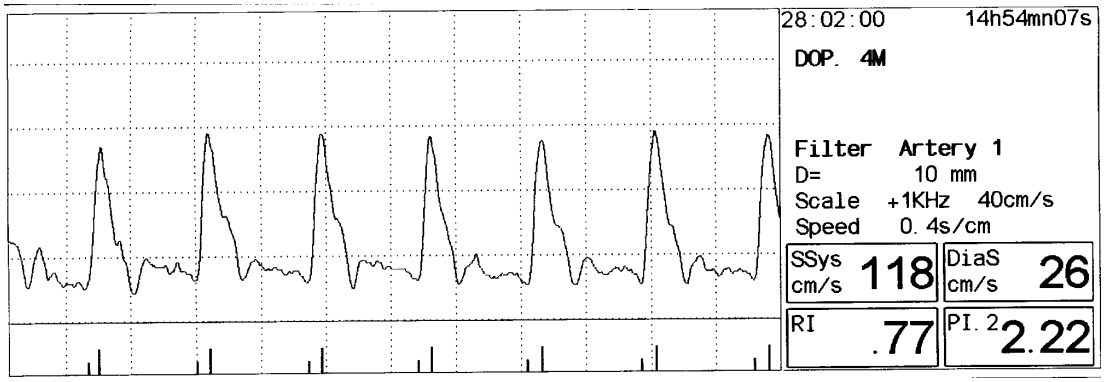
When the display offers a satisfying quality, pressing "**Pedal**" freezes the screen.
Once the acquisition is frozen:

- The curve is drawn again. Markers point out the location of systoles and diastoles.
- The displayed index calculations concern the last proper cycle for which the systole and diastole markers are displayed.
- It is still possible to change the vessel name with the "**Select vessel**" menu (press the QuickButton to reach this menu).

Scrolling

The **BASIC** automatically saves the most recent one-minute of a waveform.
Scrolling lets you view a waveform that is no longer on the screen. Since the instrument prints only the data shown on the screen, you may scroll to view the waveform you want to print. The different calculations and parameters are then updated.
Once the acquisition is frozen, turn the QuickButton counter clockwise ("**-**") to review the previous waveform.
It is also possible to change the sweep speed, sign, filter, and zero line position.

5.5. Printing



Once the acquisition is frozen, the screen can be printed out by pressing "**Pedal**":

- In the "**immediate**" printer operating mode, the system returns automatically to the acquisition mode after the printout.
- In the "**automatic**" printer operating mode, the system does not return to the acquisition mode after the printout, it remains frozen. This allows several printouts after scrolling.
  Press "**Null**" to unfreeze the acquisition.

If the "**continuous**" printer operating mode is selected, press the "**Pedal**" key to print continuously. Press again the "**Pedal**" to print the adjustment parameters and to stop the printing.

5.6. Taking systolic pressures in the Doppler mode

You can record systolic blood pressure using the Doppler mode.
Secure a pressure cuff on the arm, thigh, calf, ankle or digit you are examining.
Use the Doppler probe to locate an artery distal to the cuff.
Inflate the cuff to stop blood flow.
As the pressure cuff deflates, the **BASIC** records the returning waveform.

The systolic pressure is estimated by the pressure needed in a blood pressure cuff to stop flow. The level of measurement is determined by the site of the compressing cuff, not the flow detection site. (It is the intraluminal pressure under the cuff that must be overcome to stop flow).

The probe detects the return of the blood flow in the posterior tibial artery

The probe detects the return of the blood flow in the brachial artery

5.6.1. Detailed procedure

If not already done, select Doppler examination from **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **DOP. 4M** or **DOP. 8M**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.
  In the acquisition screen, you can switch from the 4 MHz probe to the 8 MHz probe by pressing the following key: 4/8.

Use the Doppler probe to locate an artery distal to the cuff. Obtain a good quality (clear and maximum amplitude) Doppler waveform.

- **Press "Null" to enter the pressure measurement mode.**
  The following message is displayed: **"Adjust Vess. Name NEXT : PED"**. It means that you can adjust the name and side of the vessel and then press "**Pedal**" to validate it and to go to the next step.

- If necessary, change the name of the vessel turning counterclockwise or pressing the QuickButton. According to the selected vessel territory, you may have to turn the QuickButton on 90° before displaying any vessel name.
  If you want just to change the side, press twice the QuickButton.

- Press "**Pedal**" to validate the name of the vessel.
  The following message is displayed: "**Occlusion PRESS. NEXT PED**". It means that you can now adjust the value of the cuff pressure that is supposed to be equal to the occlusion pressure. Then the next step is to press "**pedal**" to inflate the cuff.

The default value of the occlusion pressure is 100 mmHg. It is displayed in the upper left hand corner beside the label **Occl**. It can be adjusted turning the QuickButton. The occlusion value cannot be greater than 300 mmHg. The occlusion pressure must be 20 to 30 mmHg higher than the systolic pressure.

- **At this stage you have two options.**
  First option: you adjust the value of the occlusion pressure turning the QuickButton.
  Then you press "**Pedal**" to start the inflation. **Beeps must be heard before starting the pressure measurement** (they indicate that the Doppler signal is stable).
  You have to press "**Pedal**" all along the inflation. During the inflation the following message is displayed: "**Inflating PED**".
  Once the input occlusion pressure is reached the inflation stops automatically.
  Nevertheless, if you realise that the input pressure is not high enough you can resume the inflation: you have just to release the "**Pedal**" and just after press again the **"Pedal**". You have to press the "**Pedal**" until the occlusion is reached. In this case, you have to release the "**Pedal**" to stop the inflation.

  Second option: You do not adjust the occlusion pressure; you keep the default value of 100 mmHg.
  Then you press "**Pedal**" to start the inflation. **Beeps must be heard before starting the pressure measurement** (they indicate that the Doppler signal is stable).
  You have to press "**Pedal**" all along the inflation. During the inflation the following message is displayed: "**Inflating PED**".
  Once the 100 mmHg cuff pressure is reached, the inflation stops automatically. The cuff pressure is likely to be insufficient for an occlusion. You may have to resume the inflation. To do so you have just to release the "**Pedal**" and just after press again the **"Pedal**". You have to press the "**Pedal**" until the occlusion is reached. In this case, you have to release the "**Pedal**" to stop the inflation.

- After the inflation, the **BASIC** deflates the cuff automatically.
  The deflation occurs X seconds (deflation delay) after the end of the inflation. So during this time, if the input occlusion pressure is not high enough, it is possible to resume the inflation without deflating the cuff. To do so, release the "**Pedal**" and just after press again the **"Pedal**", the inflation is resumed. You can release the "**Pedal**" as soon as the occlusion is reached. The deflation occurs X seconds (deflation delay) after the end of the inflation. If the occlusion pressure is equal to 300 mmHg, X=0. Otherwise, the deflation delay can be equal to 1 to 6 s. The adjustment of this delay is performed in the **Unit configuration menu** (see § 13.6).

- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**"
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner. The cursor indicates the place where the pressure is calculated. **You can move the cursor turning the QuickButton in order to get the value of the pressure on another location**.
- When the acquisition window is frozen, it is possible to go to the **configuration menu** by pressing the QuickButton. You may have to go to the **configuration menu** to change the label of the vessel.

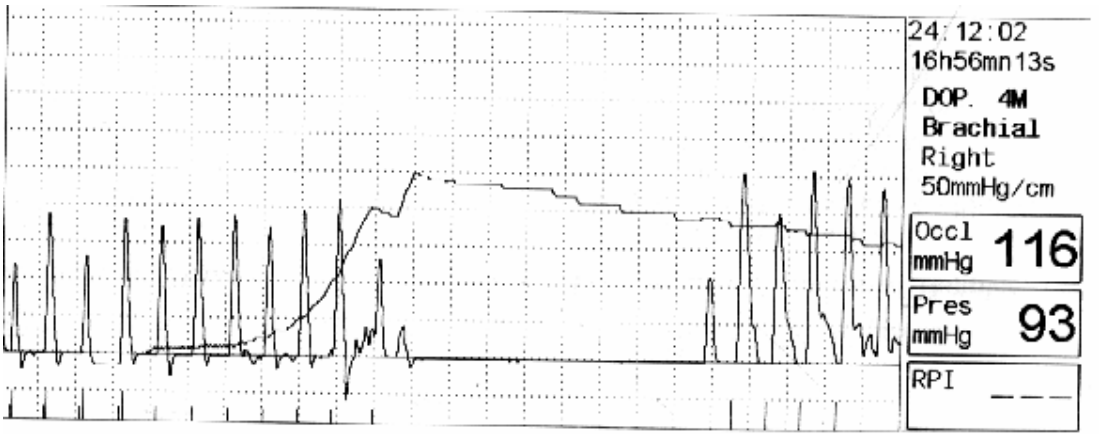
- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print the pressure.

At any time during the examination, you can press "**Null**" to leave the pressure measurement window and go back to the Doppler acquisition window. During the inflation and deflation mode, it is possible: – To leave the pressure measurement window and deflate the cuff by pressing "**Null**". – To deflate quickly the cuff by pressing "**Pedal**" (the pressure measurement window remains displayed).

5.6.2. Printout

As far as the pressure examination is concerned, two kinds of printout are available:
- A printout of the pressure values and of the curves (Doppler and pressure).
- A printout of the pressure values alone.

The selection of the kind of printout is performed in the **Unit configuration menu** (see § 13.6).



The above printout is obtained with a low sweep speed.

This key is used to adjust the sweep speed.

Once the print out is performed, the **BASIC** returns to:
- the Doppler acquisition screen if one of the following vessel territories is selected:
  - Upper.
  - Lower.
  - Cervical.
  - Miscellaneous.
- the pressure measurement screen if one of the following vessel territories is selected:
  - Pres. Lower (pressure in lower limb).
  - Pres. Upper (pressure in upper limb).

  In this case, the name of the next vessel in the list is displayed. Follow the instructions displayed on the screen to continue the pressure measurement (validation of the vessel name, adjustment of the occlusion pressure…).

5.6.3. Segmental pressure

If you want to perform a segmental pressure test in the legs, it is advised to select the following vessel territory: "**Lowers W. Pressure**".

When you perform the segmental pressure test, you suspect a blockage of blood flow in a patient's leg. With the test, you are trying to find out:

- If there is a blockage in the leg arteries.
- How much blockage there is in the leg arteries.
- Where the blockage is located.

5.6.4. Limitations of the pressure measurement with Doppler

Doppler is an effective method of measuring systolic pressures, but it does have a few limitations.

Calcium deposit and/or partially hardened arteries can give false pressure readings. In these cases, it is recommended to obtain toe pressures and PVR waveforms.

Obese and overly muscular patients may show elevated pressures, especially in thigh locations.

It is also important to listen carefully as the auditory sounds cab offer valuable insight into the vascular condition.

Probe position and technique are important in obtaining quality waveforms.

5.7. Venous Doppler exam

Use the Doppler venous exam to screen patients with suspected valvular incompetency, deep vein thrombosis or superficial thrombophlebistis.

A Doppler venous exam compares blood flow in a leg with the blood flow when the leg is compressed both distally and proximally to the probe location.
When you compress the leg distal to the probe, you force the blood to move faster toward the probe. This faster movement of the blood causes an augmented Doppler sound unless there is an obstruction in the blood vessel.
When you compress the leg proximal to the probe, you restrict the blood flow to the heart. This compression allows you to test the valves on the proximal side. If the valves are competent you should hear no Doppler sound.

Use the 4 MHz probe for this test.

You may have to explore the following sites:

- Common femoral vein.
- Superficial femoral vein.
- Popliteal vein.
- Posterior tibial vein (ankle).
- Greater saphenous vein.

6. TWO CHANNEL ARTERIAL PHOTO-PLETHYSMOGRAPHY (PPG PH2)

Use this examination to evaluate capillary blood flow in the tissues.
You can use PPG ph2 in the arterial mode to assess the arterial blood flow supply to specific location.
The venous mode is used to assess valvular sufficiency by performing a Venous Reflux Test (See § 9).

The PPG Ph2 is used for the digital test. In this exam the digits are tested bilaterally. This allows for immediate bilateral comparison.

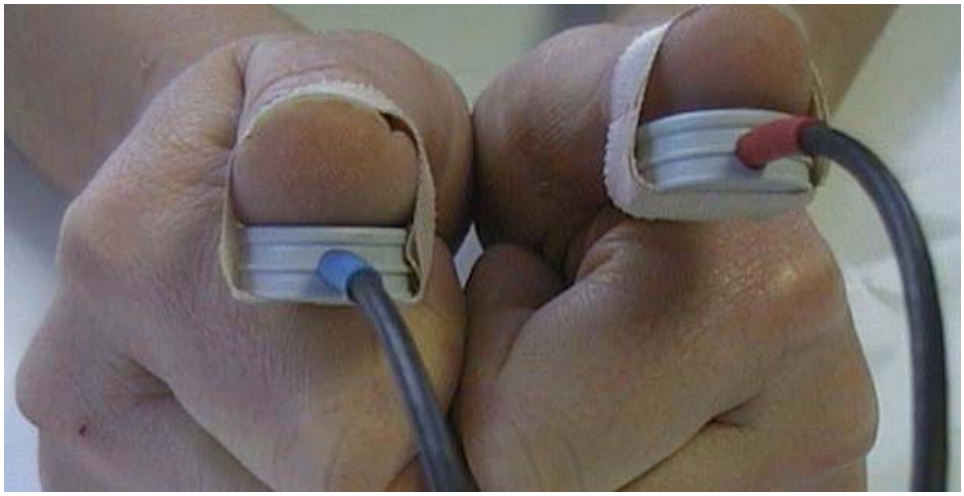
The PPG sensors comprise an infrared light emitter and a receptor.
The light emitter directs infrared light into the skin. The receptor measured the amount of light reflected off the blood cells.

The amount of blood in skin tissue changes with each heart contraction. The PPG sensors measure this change and depict it in a waveform. The greater the change in tissue perfusion from each heart beat, the more "mountainous" the waveform.

For better visualisation, you may need to increase the waveform size (with the amplitude key). However, the more you increase the size, the poorer the blood supply is to the area being examined.
In this test, the amplitude key allows to adjust the gain. The gain values are 1, 2, 5, 10, 20, 50 and 125. If the gain is equal to 125 and the waveform is still weak (small amplitude) for most of the exam sites, the tissue perfusion is very low. Conversely, if the waveform is strong (large amplitude) for most of the sites examined, the tissue perfusion is correct.

6.1. Start of the acquisition

To perform PPG ph2, connect the two arterial infrared sensors to the two connectors on the **BASIC**.
The connector in the lower right hand side corner is for the right side. The other connector is for the left side.
Place or tape the two sensors on the desired locations.



Position the patient appropriately on his/her back on the examining table. You may elevate the patient's head with pillows for greater comfort. The patients' hands should be resting comfortably on the examining table.

For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25°C. The patient must remain relaxed throughout the exam. Remind the patient to remain still and to refrain from talking.

Vasoconstricting and vasodilation agents may affect PPG signals. Use of cigarettes, coffee, vasoactive drugs or an abnormal room temperature should be noted when performing PPG exams.

Select two-channel photo-plethysmography (**PPG ph2**) in the **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **PPG ph2**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

Obtain good quality waveforms.

6.2. Adjustment

During the acquisition the user performs the following adjustments:

- Selection of the arterial mode with the "**Filter**" key. The selected filter must be **Artery**.
- Amplitude adjustment. The waveforms must be neither truncated nor too small.
- Sweep speed adjustment. The advised sweep speed is 0.4s/cm.
- Zero line adjustment.
- Selection of the vessel name (turning the QuickButton from the screen is not frozen or with the **"Select vessel"** menu).
- Selection of the printer operating mode (the Immediate mode (IMDT) is advised).

6.3. Acquisition quality

The acquisition quality can be judged according to the following criteria:

- The number and the location (one per cycle) of the systole markers have to be correct.
- The displayed heart rate is a good indicator, easy to check. It must be steady (the discrepancies between to successive cycles must not be greater than 10%) and coherent with the patient heart rate.

If no systole markers are displayed and if the indices are not calculated, it may be due to the selected amplitude. Try to increase the value of the gain (with the "**Amplitude**" key). So the height of the displayed signal will be higher. The Y-axis scale must be chosen to take advantage of the full screen. Nevertheless, the waveform must not go out of the screen otherwise the calculations are not correct.

6.4. Validation

Display freezing

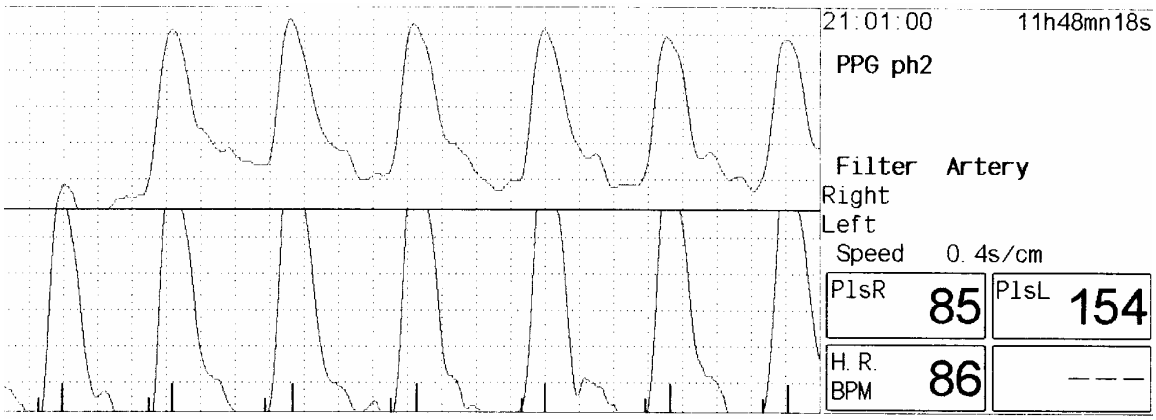
When the display offers a satisfying quality, the screen can be frozen by pressing "**Pedal**".
Once the acquisition is frozen, the curve is drawn again. Markers point out the location of systoles.
The displayed index calculations concern the last proper cycle for which the systole markers are displayed.

Once the acquisition is frozen, it is still possible to change the vessel name with the "**Select vessel**" menu (you can reach it pressing the QuickButton).

Scrolling

The **BASIC** automatically saves the most recent one-minute of a waveform.
Scrolling lets you view a waveform that is no longer on the screen. Since the instrument prints only the data shown on the screen, you must scroll to view the waveform you want to print. The different calculations and parameters are then updated.
Once the acquisition is frozen, you can turn the QuickButton counter clockwise to review the previous waveform.
It is also possible to change the sweep speed, filter, zero line position and the Y-axis scale.

6.5. Printing



Once the acquisition is frozen, the screen can be printed out by pressing "**Pedal**":

- In the "**immediate**" printer operating mode, the system returns automatically to the acquisition mode after the printout.
- In the "**automatic**" printer operating mode, the system does not return to the acquisition mode after the printout, it remains frozen. This allows several printouts after scrolling.
  Press "**Null**" to unfreeze the acquisition.

If the "**continuous**" printer operating mode is selected, press the "**Pedal**" key to print continuously. Press again the "**Pedal**" to print the adjustment parameters and to stop the printing.

7. ONE CHANNEL PHOTO-PLETHYSMOGRAPHY (PPG PH1)

The principle is the same as for two channel photo-plethysmography (see § 6).

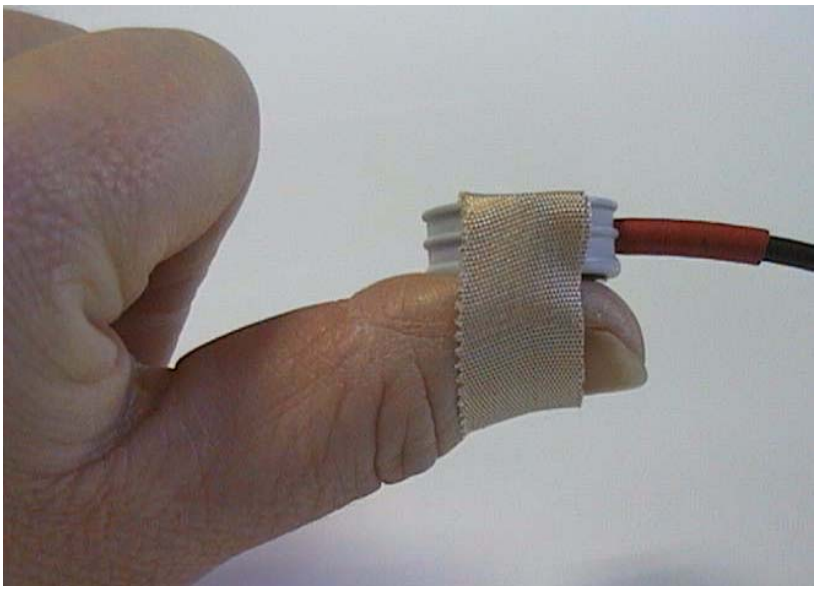
You can use PPG ph1 (one channel photo-plethysmography) in the arterial mode to assess the arterial blood flow supply to specific location.

PPG Ph1 can be used to perform digital test or to measure the strength of arterial pulsations in the tissue surrounding a wound.
By assessing relative circulation in the area of a wound, you may be able to establish a prognosis for healing.
In general, weaker arterial pulsations indicate poorer circulation.

For better visualisation, you may need to increase the waveform size (with the amplitude key). However, the more you increase the size, the poorer the blood supply is to the area being examined.
In this test, the amplitude key allows to adjust the gain. The gain values are 1, 2, 5, 10, 20, 50 and 125. If the gain is equal to 125 and the waveform is still weak (small amplitude) for most of the exam sites, the tissue perfusion is very low (in the case of a wound, there may be little chance that the wound will heal on its own). Conversely, if the waveform is strong (large amplitude) for most of the sites examined, the tissue perfusion is correct (in the case of a wound, there is a better chance for the lesion to heal on its own).

7.1. Start of the acquisition

Place or tape the sensor on the desired location.
To perform the examination, connect the arterial sensor to the left-hand side connector on the **BASIC**.



Position the patient appropriately on his/her back on the examining table. You may elevate the patient's head with pillows for greater comfort. The patient's hands should be resting comfortably on the examining table.

For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25°C. The patient must remain relaxed throughout the exam. Remind the patient to remain still and to refrain from talking.

Vasoconstricting and vasodilation agents may affect PPG signals. Use of cigarettes, coffee, vasoactive drugs or an abnormal room temperature should be noted when performing PPG exams.

Select **PPG ph1** in the **examination** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **PPG ph1**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

Select the vessel name with the QuickButton

Obtain a good quality waveform.

7.2. Adjustment

During the acquisition the user performs the following adjustments:

- Selection of the artery mode with the "**Filter**" key. Select the **Artery** filter.
- Amplitude adjustment.
- Sweep speed adjustment. The advised sweep speed is 0.4s/cm.
- Zero line adjustment.
- Selection of the vessel name.
- Selection of the printer operating mode. The Immediate mode (IMDT) is advised.

7.3. Acquisition quality

The acquisition quality can be judged according to the following criteria:

- The number and the location (one per cycle) of the systole markers have to be correct.
- The displayed heart rate is a good indicator, easy to check. It must be steady (the discrepancies between to successive cycles must not be greater than 10%) and coherent with the patient heart rate.

7.4. Validation

Display freezing

When the display offers a satisfying quality, the screen can be frozen by pressing "**Pedal**".
Once the acquisition is frozen, the curve is drawn again. Markers point out the location of systoles.
The displayed index calculations concern the last proper cycle for which the systole markers are displayed.

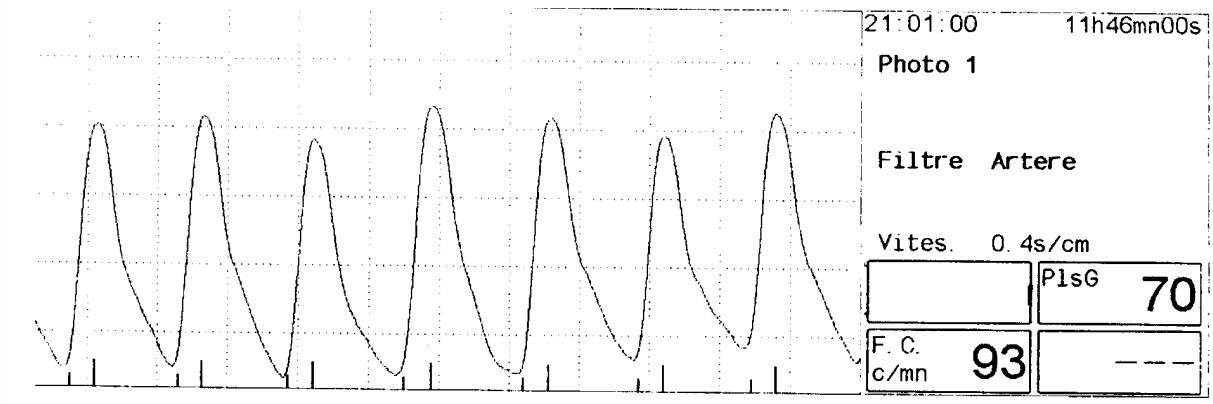
If no systole markers are displayed and if the indices are not calculated, it may be due to the selected amplitude. Try to increase the value of the gain with the "**Amplitude**" key. So the height of the displayed signal will be higher. The Y-axis scale must be chosen to take advantage of the full screen. Nevertheless, the waveform must not go out of the screen otherwise the calculations are not correct.

Scrolling

The **BASIC** automatically saves the most recent one-minute of a waveform.
Scrolling lets you view a waveform that is no longer on the screen. Since the instrument prints only the data shown on the screen, you must scroll to view the waveform you want to print. The different calculations and parameters are then updated.

Once the acquisition is frozen, you can turn the QuickButton counter clockwise to review the previous waveform.
It is also possible to change the sweep speed, sign, filter, zero line position and amplitude.

7.5. Printing



Once the acquisition is frozen, the screen can be printed out by pressing "**Pedal**":

- In the "**immediate**" printer operating mode, the system returns automatically to the acquisition mode after the printout.
- In the "**automatic**" printer operating mode, the system does not return to the acquisition mode after the printout, it remains frozen. This allows several printouts after scrolling.
  Press "**Null**" to unfreeze the acquisition.

If the "**continuous**" printer operating mode is selected, press the "**Pedal**" key to print continuously. Press again the "**Pedal**" to print the adjustment parameters and to stop the printing.

7.6. Taking systolic pressure in the one channel photo-plethysmography mode

You can record systolic blood pressure in the limbs and in the extremities while using the PPG ph1.
A cuff is secured around the arm, leg or digit you are examining.
The arterial infrared sensor is used to locate a vessel distal to the cuff (in one digit or in one toe).
The cuff is inflated to stop the blood flow.
As the pressure cuff deflates, the **BASIC** (infrared sensor) records the returning waveform.

The pressure corresponding to the return of the blood flow is the systolic pressure.
The level of measurement is determined by the site of the compressing cuff, not the flow detection site. (It is the intraluminal pressure under the cuff that must be overcome to stop flow)

7.6.1. Performing the pressure measurement in the one channel photo plethysmography mode

Connect the cuff to the **BASIC**.
Secure the cuff on the arm, leg or digit you are examining.
Place or tape an arterial infrared sensor on a digit or toe depending on the location you are testing.

If not already done, select **PPG ph1** examination from **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **PPG ph1**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

Obtain a good quality waveform.

- **Press "Null" to enter the pressure measurement mode.**
  The following message is displayed: **"Adjust Vess. Name NEXT : PED"**. It means that you can adjust the name and side of the vessel and then press "**Pedal**" to validate it and to go to the next step.

- If necessary, change the name of the vessel turning counterclockwise or pressing the QuickButton. According to the selected vessel territory, you may have to turn the QuickButton on 90° before displaying any vessel name.
  If you want just to change the side, press twice the QuickButton.

- Press "**Pedal**" to validate the name of the vessel.
  The following message is displayed: "**Occlusion PRESS. NEXT PED**". It means that you can now adjust the value of the cuff pressure that is supposed to be equal to the occlusion pressure. Then the next step is to press "**pedal**" to inflate the cuff.
  The default value of the occlusion pressure is 100 mmHg. It is displayed in the upper left hand corner beside the label **Occl**. It can be adjusted turning the QuickButton.
  The occlusion value cannot be greater than 300 mmHg. The occlusion pressure must be 20 to 30 mmHg higher than the systolic pressure.

- **At this stage you have two options.**
  First option: you adjust the value of the occlusion pressure turning the QuickButton.
  Then you press "**Pedal**" to start the inflation. **Beeps must be heard before starting the pressure measurement** (they indicate that the photo plethysmography signal is stable).
  You have to press "**Pedal**" all along the inflation for safety reason. During the inflation the following message is displayed: "**Inflating PED**".
  Once the input occlusion pressure is reached the inflation stops automatically.
  Nevertheless, if you realise that the input pressure is not high enough for the occlusion, you can resume the inflation: you have just to release the "**Pedal**" and just after press again the **"Pedal**".
  You have to press the "**Pedal**" until the occlusion is reached. In this case you have to release the "**Pedal**" to stop the inflation.

  Second option: you do not adjust the occlusion pressure; you keep the default value of 100 mmHg.
  Then you press "**Pedal**" to start the inflation. **Beeps must be heard before starting the pressure measurement** (they indicate that the photo plethysmography signal is stable).
  You have to press "**Pedal**" all along the inflation for safety reason. During the inflation the following message is displayed: "**Inflating PED**".
  Once the 100 mmHg cuff pressure is reached, the inflation stops automatically. The cuff pressure is likely to be insufficient for an occlusion. You may have to resume the inflation. To do so, you have just to release the "**Pedal**" and just after press again the **"Pedal**". You have to press the "**Pedal**" until the occlusion is reached. In this case, you have to release the "**Pedal**" to stop the inflation.

- After the inflation, the **BASIC** deflates the cuff automatically.
  The deflation occurs X seconds (deflation delay) after the end of the inflation. So during this time, if the input occlusion pressure is not high enough, it is possible to resume the inflation without deflating the cuff. To do so, release the "**Pedal**" and just after press again the **"Pedal**", the inflation is resumed. You can release the "**Pedal**" as soon as the occlusion is reached. The deflation occurs X seconds (deflation delay) after the end of the inflation. If the occlusion pressure is equal to 300 mmHg, X=0. Otherwise, the deflation delay can be equal to 1 to 6 s. The adjustment of this delay is performed in the **Unit configuration menu** (see § 13.6)

- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- When the acquisition window is frozen, it is possible to go to the **configuration menu** by pressing the QuickButton. You may have to go to the **configuration menu** to change the label of the vessel.

- **Press:**
  - "**Null**" to return to the Doppler examination window without printing.
  - "**Pedal**" to print the pressure.

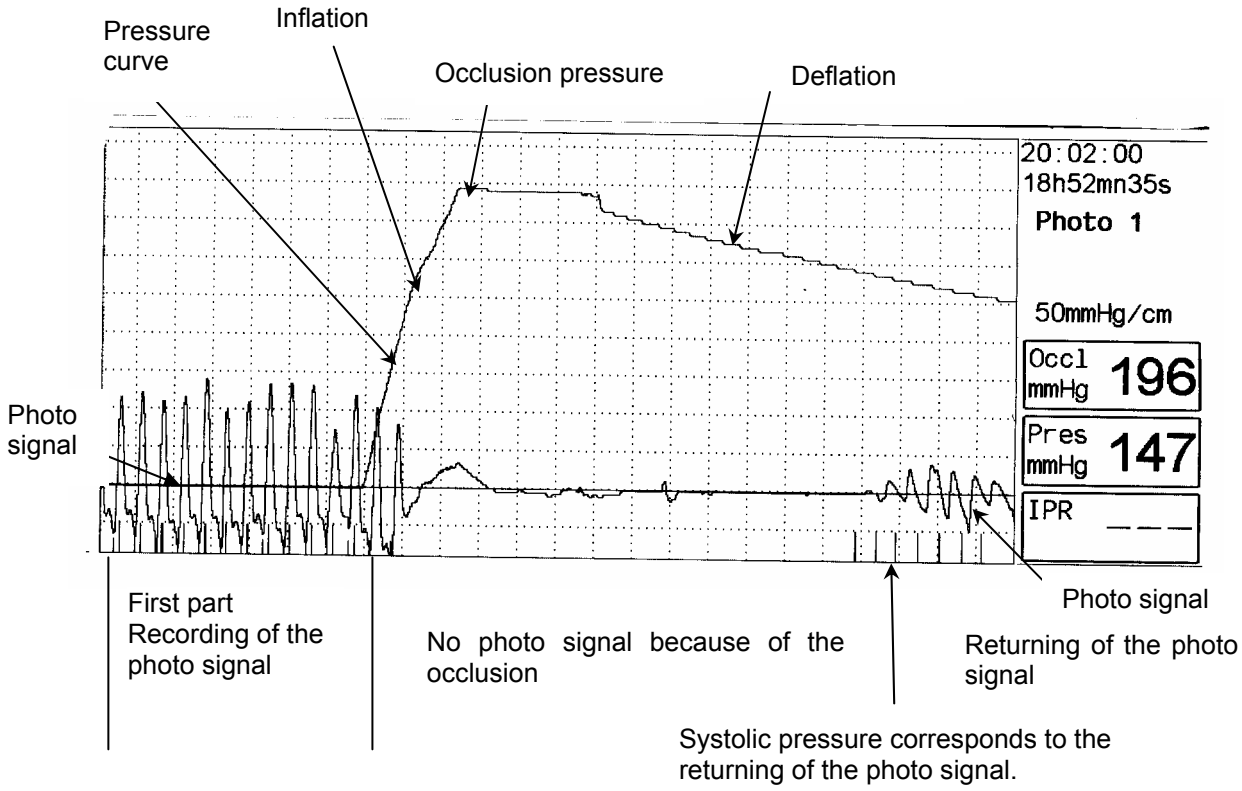
At any time during the examination, you can press "**Null**" to leave the pressure measurement window and go back to the Doppler acquisition window. During the inflation and deflate mode it is possible: – To leave the pressure measurement window and deflate the cuff by pressing "**Null**". – To deflate quickly the cuff by pressing "**Pedal**" (the pressure measurement window remains displayed).

7.6.2. Printout

As far as the pressure examination is concerned, two kinds of printout are available:

- A printout of the pressure values and of the curves (Doppler and pressure).
- A printout of the pressure values alone.

The selection of the kind of printout is performed in the **Unit configuration menu** (see § 13.6).



The above printout is obtained with a low sweep speed.

This key is used to adjust the sweep speed.

Once the print out is performed, the **BASIC** returns to:

- The acquisition screen if one of the following vessel territories is selected:
  - Upper.
  - Lower.
  - Cervical.
  - Miscellaneous.
- To the pressure measurement screen if one of the following vessel territories is selected:
  - Pres. Lower (pressure in lower limb).
  - Pres. Upper (pressure in upper limb).

  In this case, the name of the next vessel in the list is displayed. Follow the instructions displayed on the screen to continue the pressure measurement (validation of the vessel name, adjustment of the occlusion pressure…).

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print the pressure.

7.7. Limitation of the pressure measurement with PPG

Because the PPG sensor is very sensitive to light and movement, it is possible to obtain incorrect systolic pressures if a patient moves or talks.
Incorrect systolic pressures may also be obtained from a moderate or severely diseased patient because their capillary blood flow is often compromised.
If either of these cases occurs, you will have to use the Doppler mode to obtain systolic pressure.

8. ONE CHANNEL PNEUMO-PLETHYSMOGRAPHY–PULSE VOLUME RECORDING

Use the one channel pneumo-plethysmography arterial mode to record arterial pulse wave shape and amplitude at various limb or digit locations. This information allows you to assess the circulation at those locations.

PVR uses air filled cuff to record changes of blood volume in a limb.
By wrapping the pressure cuff around different locations on patient's legs, arms or digits, you can quickly assess blood flow at these locations

Relative limb volume increases with each heartbeat. PVR measures this increase and depicts it in a waveform.

PVR is used in conjunction with segmental blood pressures and Doppler waveform analysis to fully evaluate the patient with peripheral vascular disease.

8.1. Start of the acquisition

Secure a cuff on the location under examination.

Position the patient appropriately on his/her back on the examining table. You may elevate the patient's head with pillows for greater comfort.

For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25°C. The patient must remain relaxed throughout the exam. Remind the patient to remain still and to refrain from talking.

To perform the examination, connect the cuff to the **BASIC**.

Select **PVR pn1** in the **examination** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **PVR pn1**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

Select the **artery** mode with the "**Filter**" key.

Obtain a good quality waveform.

- **Press "Null" to enter the pressure measurement mode.**
  The following message is displayed: "**Adjust Cuff Pres. NEXT : PED**" It means that you can adjust the cuff pressure. The next step is to press "**Pedal**" to inflate the cuff. The default value of the cuff pressure is 60 mmHg. It cannot be greater than 110 mmHg.

- If necessary, change the cuff pressure turning the QuickButton.
- **Press the foot pedal to inflate the cuff to the set pressure.**
  The user has to press the foot pedal all along the inflation. Otherwise the inflation is stopped.

The volume changes are recorded.

- Press "**Pedal**" to stop the recording, deflate the cuff and freeze the screen.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print the pressure.

At any time during the examination press:
- "**Null**" to deflate the cuff. The displayed window allows you to change the value of the set pressure and to resume the examination. Press "**Null**" again to leave this window.
- "**Pedal**" to freeze the acquisition window and deflate the cuff.

8.2. Adjustment

During the acquisition the user performs the following adjustments:

- Selection of the artery mode with the "**Filter**" key. The **artery** filter must be selected.
- Amplitude adjustment.
- Sweep speed adjustment. The advised sweep speed is 0.4s/cm.
- Zero line adjustment.
- Selection of the printer operating mode. The Immediate mode (IMDT) is advised.
- Selection of the vessel name (turning the QuickButton or with the **"Select vessel"** menu).

8.3. Acquisition quality

The acquisition quality can be judged according to the following criteria:
- The number and the location (one per cycle) of the systole markers have to be correct.
- The displayed heart rate is a good indicator, easy to check. It must be steady (the discrepancies between to successive cycles must not be greater than 10%) and coherent with the patient heart rate.

If no systole markers are displayed and if the indices are not calculated, it may be due to the selected amplitude. Try to decrease the value of the scale of the y-axis (with the "**Amplitude**" key). So the height of the displayed signal will be higher. The Y-axis scale must be chosen to take advantage of the full screen. Nevertheless, the waveform must not go out of the screen otherwise the calculations are not correct.

8.4. Validation

Display freezing
When the display offers a satisfying quality, the screen can be frozen by pressing "**Pedal**".
Once the acquisition is frozen, the curve is drawn again. Markers point out the location of systoles.
The displayed index calculations concern the last proper cycle for which the systole markers are displayed.

Scrolling

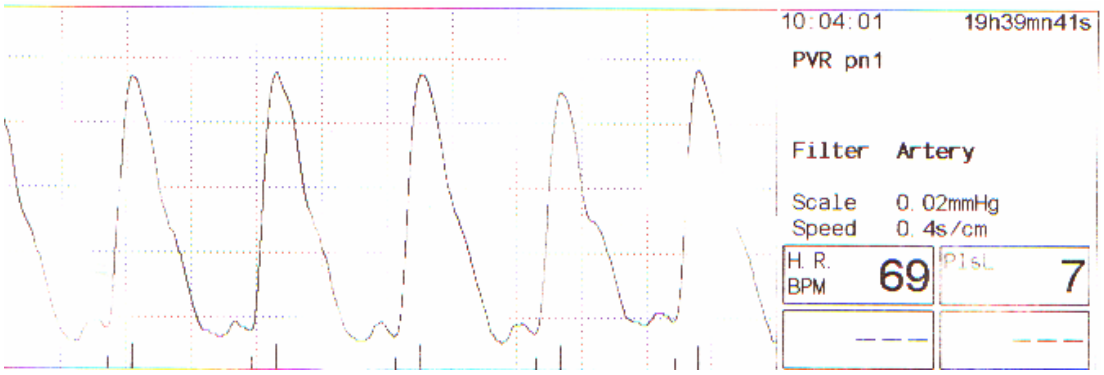
The **BASIC** automatically saves the most recent one-minute of a waveform.
Scrolling lets you view a waveform that is no longer on the screen. Since the instrument prints only the data shown on the screen, you must scroll to view the waveform you want to print. The different calculations and parameters are then updated.
Once the acquisition is frozen, you can turn the QuickButton counter clockwise to review the previous waveform.
It is also possible to change the sweep speed, sign, filter, zero line position and amplitude.

8.5. Printing

Once the acquisition is frozen, the screen can be printed out by pressing "**Pedal**":

- In the "**immediate**" printer operating mode, the system returns automatically to the acquisition mode after the printout.
- In the "**automatic**" printer operating mode, the system does not return to the acquisition mode after the printout, it remains frozen. This allows several printouts after scrolling.
  Press "**Null**" to unfreeze the acquisition.

If the "**continuous**" printer operating mode is selected, press the "**Pedal**" key to print continuously. Press again the "**Pedal**" to print the adjustment parameters and to stop the printing.



9. VENOUS REFLUX TEST

Use the Venous Reflux Test to evaluate valve competency of the patient's superficial and deep venous systems in both legs.

In a normal patient, competent valves in the venous system of the legs prevent reflux of the blood (backflow of the blood in the veins). In this test, photo-plethysmography is used to measure changes in the capillary blood flow. The photo-plethysmography probe records instantaneous changes in the blood content of the skin that occur when there are changes in the venous pressure.

The printed results include the venous reflux waveforms and an indication of the interval of time required to refill the venous system. These results allow the physician to determine whether to perform further evaluation of the patient's venous system.

9.1. Start of the acquisition

For accurate exam results, the patient must be warm. The room temperature should be between 22°C and 25°C. The patient must also rest quietly for two minutes before you begin the test. If necessary, dim the lights while the patient rests.

For accurate test results, remind the patient to sit still and to refrain from talking throughout the Venous Reflux Test. It is very important for the patient to rest, without talking or moving his/her legs, for a full two minutes before performing the calf exercises.

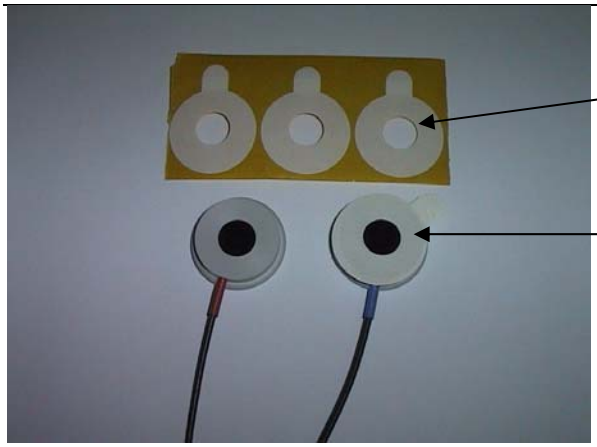
First perform the Venous Reflux Test without placing a tourniquet on the patient. This test allows you to evaluate the patient's superficial and deep venous systems. If the test results are abnormal, repeat the test after placing a pressure cuff on the patient's thigh. The pressure cuff acts as a tourniquet that excludes the effect of the superficial system to allow testing of the deep system.

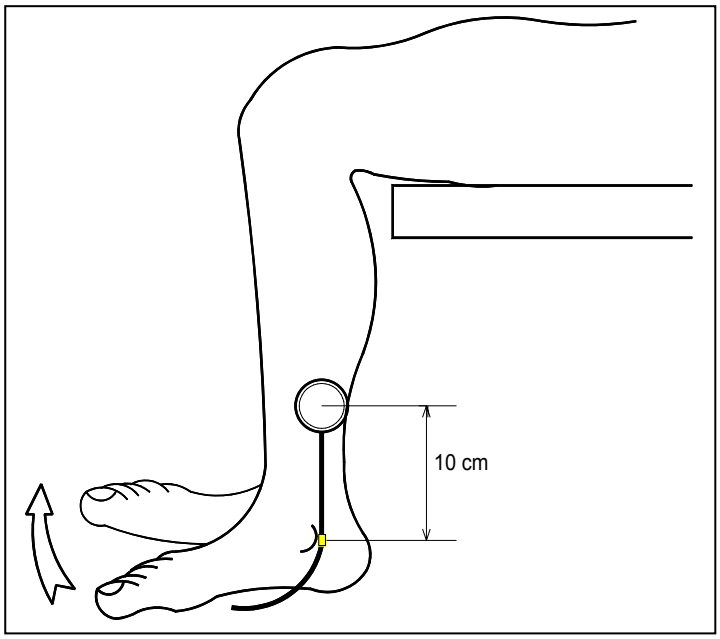
To perform the Venous Reflux Test, prepare the patient:

- Attach an adhesive pad to the sensor side of each disk. Remember to use an adhesive pad only once since it may lose some of its adhesion when moving from site to site and then not stick to the skin throughout the test.

- Attach the PPG probe to the skin within the distance range distal to the ankle bone (see figure). This distance is indicated by a mark on the sensor cable. Align the cord with the ankle bone and attach the venous photo-plethysmography sensor to the leg. It is recommended that the probe be attached so that the cord hangs down the leg, toward the ankle, thus reducing the chance of it pulling away from the skin.

Have the patient sit on a chair or padded table with his/her feet flat on the floor. Make sure there is no constriction under the patient's legs. You may have to shave the body hair before adhering the probes to the skin surface. The ideal probe position varies from patient to patient. If you do not get a good waveform, reposition the probe closer to the ankle.


Adhesive pad
Sensor with an adhesive pad



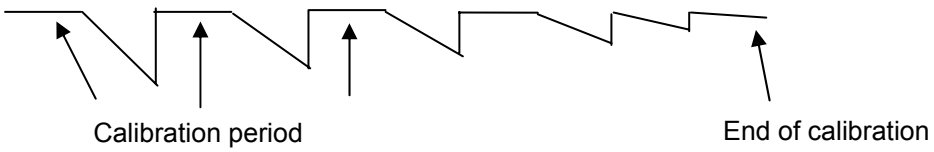
During the examination, messages are displayed on the lower part of the screen to let you know what to do.

Select Venous Reflux Test (V.R.T.) in the **examination** selection menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **V.R.T.**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

You can either press:
- "**Null**" to start the examination.
- "**Enter**" to go to the **configuration menu** in order to select another examination and so to leave the V.R.T.
- "**Pedal**"; this action freezes the screen; press "**Null**" to unfreeze it.

- **Press "Null" to start the test**
- The examination starts with a calibration. The following message is displayed on the screen "**1 calibrating wait**". The calibration lasts 5 s.
- After the calibration period, the signal is displayed during 5 s with the following message:"**2 <PEDAL> to continue**". It means that you have to press "**Pedal**" to go to the next step.
  The signal must be stable to go to the next step.
  If the signal is not stable wait for another calibration. Perform as many calibrations as necessary to get a rather stable signal.



- Press "Pedal" at the end of calibration (when the signal is stable).
  The following message is displayed: "**3 pump when buzz**"
  At the first beep, have the patient begin the flex exercises.
  There are nine beeps. Patient should flex his/her feet at each beep (about every 1.5 s).

For accurate exam results, the venous system must be emptied of blood. To empty the venous system, it is more important that the patient perform full flex exercises than he/she performs all 9 exercises.

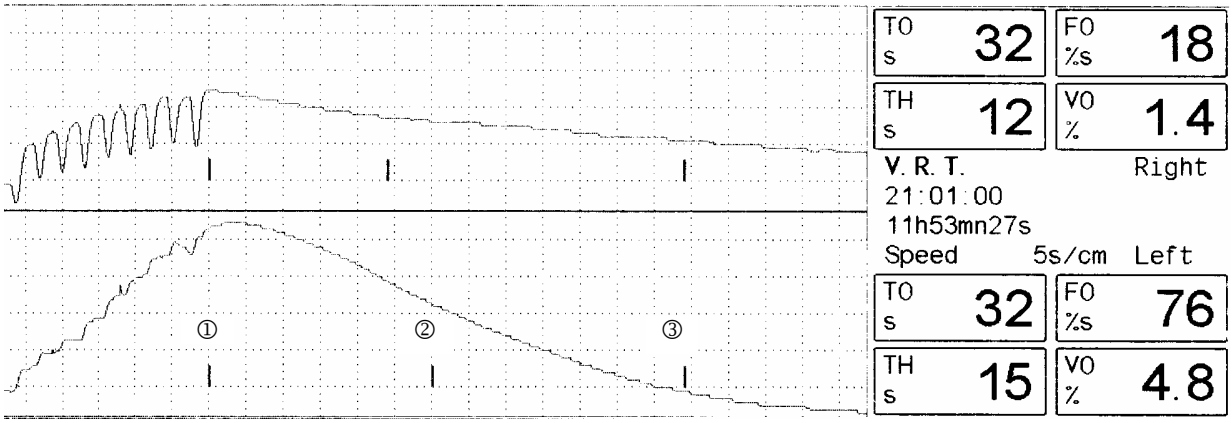
- At the end of the flex exercise, the following message is displayed: "**4 recording : wait**".
  Have the patient relax his/her feet and rest while the veins refill with blood (during around 1 min).

- After the rest period, the acquisition is frozen. For each side, the TO (time outflow) and TH (half time outflow) indices are displayed. They are calculated at the position of the cursors.
  It is possible to move the cursor turning the QuickButton. Press the QuickButton to switch from one cursor to the other.
  The following message is displayed: "**5 <PEDAL> to print**".

- **Press:**
  - "**Pedal**", to print the display.
  - "**Null**" to go back to the beginning of the V.R.T.
    Then press:
    . **"**Null**" to start a new V.R.T.**
    . **"**Enter**" to select other examination**

If you press "**Pedal**" during the flex exercises or the rest period, the acquisition will be finished. The screen is frozen.
Then press:
- "**Pedal**" to print the display.
- "**Enter**" to select and turn the QuickButton to move the cursor.
- "**Null**" to go back to the beginning of the V.R.T.
  Here press:
  - "Null" to start a new V.R.T.
  - "Enter" to select other examination.

9.2. Printing



Comment:
The refilling time is calculated from the end of the flex exercises ① up to ③.

9.3. Adjustment

During the acquisition the user performs the following adjustment:
- Adjustment of the location of the zero line.

9.4. Examination with a tourniquet

If the exam results are abnormal (<20 s), repeat the exam with a tourniquet on the patient's thigh.
The tourniquet test is necessary only if the right leg, left leg or both legs tests are abnormal.
Wrap a 12 cm pressure cuff on the right and left patient's thigh.
These cuffs are not inflated by the **BASIC**. They must be inflated by the user.
Repeat the V.R.T. as previously.

9.5. Limitations of the V.R.T.

Because the PPG probes are very sensitive to light and movement, it is important to position them correctly.
Make sure that the probes are not placed on the bone and that they make good contact with the skin.

Patients with severe venous disease may have minimal venous emptying because of immediate back flow between dorsal flexions.
A venous thrombosis may also limit venous emptying.

Performing the flex exercises may be difficult for some patients. It may be necessary to manually compress the patient's calves to empty the veins.

10. ABI TEST WITH PHOTOPLETHYSMOGRAPHY

This test allows to screen a patient for arterial disease in the lower extremities.
This exam uses:

- A photoplethysmography sensor to sense the patient's blood flow.
- A pressure cuff to measure the systolic pressure.

This test determines the Ankle/Brachial Index.
In the **BASIC** ABI is label RPI (Residual Pressure Index).

$$ABI=\frac{\text{Ankle systolic pressure}}{\text{Highest brachial pressure}}$$

The following measurements are to be performed successively:

- Right brachial systolic pressure.
- Left brachial systolic pressure.
- Right ankle systolic pressure.
- Left ankle systolic pressure.

The RPI (Residual Pressure Index) is more general than the ABI.
RPI = systolic pressure of any location/Highest brachial pressure.
For RPI test you can follow the ABI procedure but the location of the cuff is different.

10.1. Right brachial systolic pressure

Secure a cuff around the patient's right arm.
Tape an infrared arterial sensor on a patient's right digit.
The procedure is the same as described in § 7.6.

If not already done, select **PPG ph 1** examination from **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **PPG ph 1**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

If not already done, select the vessel territory (Lowers W pressure), side (right) and name (brachial):

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Select vessel**".
- Press the QuickButton. The cursor is on the vessel territory.
- Press the QuickButton and turn it to select the lower limb territory with pressure measurement: "**Lowers W. Pressure**".
- Press the QuickButton to validate.
- To change the vessel side, put the cursor on the side field. Press the QuickButton to validate. Turn the QuickButton to select the side. Press the QuickButton to validate.
- Turn the QuickButton to put the cursor on brachial.
- Press the QuickButton to validate. The **BASIC** returns to the acquisition screen.

- **Press "Null" to enter the pressure measurement mode.**
  The following message is displayed: **"Adjust Vess. Name NEXT : PED"**.

- Press "**Pedal**" to validate the name of the vessel and go to the next step.
  The following message is displayed: "**Occlusion PRESS. NEXT PED**". It means that you can now adjust the value of the cuff pressure that is supposed to be equal to the occlusion pressure. The next step is to press "**pedal**" to inflate the cuff.
  The default value of the occlusion pressure is 100 mmHg. It is displayed in the upper left hand corner beside the label **Occl**. It can be adjusted turning the QuickButton. The occlusion value

cannot be greater than 300 mmHg. The occlusion pressure must be 20 to 30 mmHg higher than the systolic pressure.

- **Press the foot pedal to inflate the cuff.** Beeps must be heard before starting the pressure measurement (see § 7.6.1).
  For safety, the user has to press the foot pedal all along the inflation. Otherwise the inflation is stopped.
  During the inflation the following message is displayed: "**Inflating PED**".

  The **BASIC** inflates the cuff up to the input occlusion pressure and then deflates the cuff automatically.

  The deflating occurs X seconds (deflation delay) after the end of the inflating. So during this time, if the input occlusion pressure is not high enough for the occlusion, it is possible to resume the inflation without deflating the cuff. To do so, release the "**Pedal**" and just after press again the **"Pedal**", the inflation is resumed. You have to release the "**Pedal**" as soon as the occlusion is reached.

- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner. The cursor indicates the place where the pressure is calculated. Turn the push QuickButton to move the cursor in order to get the value of the pressure on another location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print and save the brachial pressure. The saved brachial pressure is the one that is used for the ABI calculation. After the printout, the **BASIC** is ready for another pressure measurement. See § 7.6.2, to select the proper printout option.

10.2. Left brachial systolic pressure

The left brachial pressure is measured just to compare it with the right one.

- Secure a cuff around the patient's left arm.
- Tape an infrared arterial sensor on a patient's left digit.

- Turn the QuickButton to select the proper vessel name: **brachial**.
- Press twice the QuickButton to display left instead of right.
- Press "**Pedal**".
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you will start to inflate the cuff up to 100 mmHg and then you will resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal (see § 7.6.1). You will release the foot pedal when the occlusion is performed (the photoplethysmography signal has disappeared).
- Press "**Pedal**" to start the inflation. You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- **If the left brachial pressure is lower than the right one:**
  - Press "**Null**" to return to the acquisition screen without printing and without saving the left brachial pressure.

- **If the left brachial pressure is higher than the right one:**
  - Press "**Pedal**" to print and save the left brachial pressure. The right brachial pressure is erased. The saved brachial pressure is the one that is used for the ABI calculation. After the printout, the **BASIC** is ready for another pressure measurement.

Comment: Unless there are extenuating circumstances, the brachial pressures should be within 20 mmHg of each other. If the pressure difference is greater than 20 mmHg, retesting is recommended.

10.3. Right ankle systolic pressure

After this measurement the right ABI (RPI) will be calculated.
Secure a cuff around the patient's right ankle.
Tape an infrared arterial sensor on a patient's right toe.

- Turn the QuickButton to select the proper vessel name. You will not find Ankle; you can select for example Tibial.
- Press twice the QuickButton to display **right**.
- Press "**Pedal**".
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you start to inflate the cuff up to 100 mmHg and then you resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal. Release the foot pedal when the occlusion is performed (the photoplethysmography signal has disappeared).
- Press "**Pedal**". You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure and ABI (RPI) value are displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on an other location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print the ankle pressure. The **BASIC** is ready for another pressure measurement. See § 7.6.2, to select properly the printout option.

10.4. Left ankle systolic pressure

After this measurement the left ABI (RPI) will be calculated.
Secure a cuff around the patient's left ankle.
Tape a infrared arterial sensor on a patient's left toe.

- Turn the QuickButton to select the proper vessel name. You will not find Ankle; you can select for example Tibial.
- Press twice the QuickButton to display **left**.
- Press "**Pedal**".
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you start to inflate the cuff up to 100 mmHg and then you resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal. Release the foot pedal when the occlusion is performed (the photoplethysmography signal has disappeared).
- Press "**Pedal**". You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure and the ABI (RPI) value are displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. Turn the push QuickButton to move the cursor in order to get the value of the pressure on another location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print the ankle pressure. The **BASIC** is ready for another pressure measurement. See § 7.6.2, to select properly the printout option.

11. ABI TEST WITH DOPPLER

This test allows to screen a patient for arterial disease in the lower extremities.
This exam uses:

- A Doppler probe to sense the patient's blood flow.
- A pressure cuff to measure the systolic pressure.

This test determines the Ankle/Brachial Index.
In the **BASIC** ABI is label RPI (Residual Pressure Index).

$$ABI=\frac{\text{Ankle systolic pressure}}{\text{Highest brachial pressure}}$$

The following measurements are to be performed successively:

- Right brachial systolic pressure
- Left brachial systolic pressure
- Right ankle systolic pressure
- Left ankle systolic pressure

The RPI (Residual Pressure Index) is more general than the ABI.
RPI = systolic pressure of any location/Highest brachial pressure.
For RPI test you can follow the ABI procedure but the location of the cuff is different.

11.1. Right brachial systolic pressure

Secure a cuff around the patient's right arm.
The procedure is the same as described in § 5.6.
Use the 8 MHz probe.

If not already done, select **DOP 8** examination from **examination selection** menu:

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Examination (if not frozen)**".
- Press the QuickButton.
- Turn the QuickButton to put the cursor on **D0P 8**.
- Press the QuickButton. The **BASIC** returns automatically to the acquisition screen.

If not already done, select the vessel territory (Lowers W pressure), side (right) and name (brachial):

- From the acquisition screen press the QuickButton.
  The **configuration menu** is displayed.
- Turn the QuickButton counterclockwise to put the cursor on "**Select vessel**".
- Press the QuickButton. The cursor is on the vessel territory.
- Press the QuickButton and turn it to select the lower limb territory with pressure measurement: "**Lowers W. Pressure**".
- Press the QuickButton to validate.
- To change the vessel side, put the cursor on the side field. Press the QuickButton to validate. Turn the QuickButton to select the side. Press the QuickButton to validate.
- Turn the QuickButton to put the cursor on brachial.
- Press the QuickButton to validate. The **BASIC** returns to the acquisition screen.

Position the Doppler probe on an artery distal to the cuff. Obtain a good quality (clear and maximum amplitude) Doppler waveform.

You must hold the Doppler probe steady. Resting your hand against the patient's arm often helps.

- **Press "Null" to enter the pressure measurement mode.**
  The following message is displayed: **"Adjust Vess. Name NEXT : PED"**. You can still adjust the vessel name turning or pressing the QuickButton.

- Press "**Pedal**" to validate the name of the vessel and go to the next step.
  The following message is displayed: "**Occlusion PRESS. NEXT PED**". It means that you can now adjust the value of the cuff pressure that is supposed to be equal to the occlusion pressure. The next step is to press "**pedal**" to inflate the cuff.
  The default value of the occlusion pressure is 100 mmHg. It is displayed in the upper left hand corner beside the label **Occl**. It can be adjusted turning the QuickButton. The occlusion value cannot be greater than 300 mmHg.

- **Press the foot pedal to inflate the cuff.** Beeps must be heard before starting the pressure measurement.
  For safety, the user has to press the foot pedal all along the inflation. Otherwise the inflation is stopped.
  During the inflation the following message is displayed: "**Inflating PED**".

  The **BASIC** inflates the cuff up to the input occlusion pressure and then deflates the cuff automatically.

  The deflating occurs X seconds (deflation delay) after the end of the inflating. So during this time, if the input occlusion pressure is not high enough, it is possible to resume the inflating without deflating the cuff. To do so, release the "**Pedal**" and just after press again the **"Pedal**", the inflating is resumed. You can release the "**Pedal**" as soon as the occlusion is reached. The occlusion pressure must be 20 to 30 mmHg higher than the systolic pressure.

- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print and save the brachial pressure. The saved brachial pressure is the one that is used for the ABI calculation. After the printout, the **BASIC** is ready for another pressure measurement. See § 7.6.2, to select properly the printout option.

11.2. Left brachial systolic pressure

The left brachial pressure is measured just to compare it with the right one.

- Secure a cuff around the patient's left arm.
- Use the 8 MHz probe.

- Turn the QuickButton to select the proper vessel name: brachial.
- Press twice the QuickButton to display left instead of right.
- Press "**Pedal**"
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you start to inflate the cuff up to 100 mmHg and then you resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal. Release the foot pedal when the occlusion is performed (the Doppler signal has disappeared).
- Press "**Pedal**". You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflating, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure value is displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- **If the left brachial pressure is lower than the right one:**
  - Press "**Null**" to return to the acquisition screen without printing and without saving the left brachial pressure.

- **If the left brachial pressure is higher than the right one:**
  - Press "**Pedal**" to print and save the left brachial pressure. The right brachial pressure is erased. The saved brachial pressure is the one that is used for the ABI calculation. After the printout, the **BASIC** is ready for another pressure measurement.

Comment: Unless there are extenuating circumstances, the brachial pressures should be within 20 mmHg of each other. If the pressure difference is greater than 20 mmHg, retesting is recommended

11.3. Right ankle systolic pressure

After this measurement the right ABI (RPI) will be calculated.
Secure a cuff around the patient's right ankle.
Use the 8 MHz probe.

- Turn the QuickButton to select the proper vessel name. You will not find Ankle; you can select for example posterior tibial or dorsalis pedis.
- Press twice the QuickButton to display **right**.
- Press "**Pedal**".
- Position the Doppler probe over the posterior tibial or dorsalis pedis artery. Obtain a good Doppler signal.
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you start to inflate the cuff up to 100 mmHg and then you resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal. Release the foot pedal when the occlusion is performed (the Doppler signal has disappeared).
- Press "**Pedal**". You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure and ABI (RPI) value are displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print and save the ankle pressure. The **BASIC** is ready for another pressure measurement. See § 7.6.2, to select properly the printout option.

11.4. Left ankle systolic pressure

After this measurement the left ABI (RPI) will be calculated.
Secure a cuff around the patient's left ankle.
Use the 8 MHz probe.

- Turn the QuickButton to select the proper vessel name. You will not find ankle; you can select for example posterior tibial or dorsalis pedis.
- Press twice the QuickButton to display **left**.
- Press "**Pedal**".
- Input the occlusion pressure turning the QuickButton. The 100 mmHg default value could be convenient. If you keep the default value, you start to inflate the cuff up to 100 mmHg and then you resume the inflating up to the real occlusion pressure by releasing and pressing again the foot pedal. Release the foot pedal when the occlusion is performed (the Doppler signal has disappeared).
- Press "**Pedal**". You must press the foot pedal all along the inflating.
- As the pressure cuff deflates, the **BASIC** records the returning waveform.
  During the deflation, the following message is displayed: "**Deflating STOP : PED**".
  Once the signal is returned, you can press "**Pedal**" to deflate quickly the cuff.

- Once the cuff is deflated, the screen is frozen.

- The systolic pressure and the ABI (RPI) value are displayed on the upper left-hand side corner beside the label **Pres**. The cursor indicates the place where the pressure is calculated. You can move the cursor turning the QuickButton in order to get the value of the pressure on another location of the cursor.

- **Press:**
  - "**Null**" to return to the acquisition screen without printing.
  - "**Pedal**" to print and save the ankle pressure. The **BASIC** is ready for another pressure measurement. See § 7.6.2, to select properly the printout option.

12. EXAMINATION STORAGE IN THE BASIC

12.1. Description

The **BASIC** storage system allows to store **BASIC** examination images: Doppler, plethysmography and pressure measurement.
These images are stored in archives.

An archive includes 1 to 16 images. The storage capacity is 120 images for at most 16 archives.

The stored images can be displayed again and printed out either on the integrated thermal printer or in the PC fitted with the WinAtys software and a RS232 connection.

An archive must be open to allow the storage of images.

When an archive is open, the images are stored instead of printed out.

Comments:
- Once the archive is closed, it is no longer possible to store a new image in this archive. A new archive must be open.
- It is possible to create an archive whenever during the acquisition or when the display is frozen.

12.2. Image storage

Two lines of the **configuration menu** are dedicated to the storage.
These two lines depend on the status of the storage system, whether it is activated or not.

12.2.1.Configuration menu when no archive is open

Press the QuickButton to display the **configuration menu**.

```
Exit
.
.
.
New Archive
Archives :    4 archives     32 images
```

Configuration menu: Archives : 4 archives 32 images
Indication of the number of stored archives and images.

Configuration menu: New archive
Allows to create a new archive. Its name is input with the following menu «New Archive».

If you put the cursor on **New archive** and press QuickButton the **New archive menu** is displayed:

```
New Archive

      Date :      04/09/2001  15:12:24
      Name :      PATIENT 1
                        ^
```

The name is input with the QuickButton:
- Turn the QuickButton to select a character (letter or figure).
- Press the QuickButton to validate the selected character and to go to the next character field.

Pressing two times the QuickButton validates the name and the **BASIC** returns automatically to the acquisition screen.
When an archive is open, the print out is no longer performed on the integrated thermal printer or on the PC. The images are automatically stored in the BASIC.

12.2.2. Configuration menu when an archive is open

```
Exit
.
.
Close Archive
Archives :    4 archives     32 images
```

To close an archive, move the cursor on **Close Archive** and press the QuickButton. The **BASIC** returns automatically to the acquisition screen.
When the archive is closed, it is possible to open a new one (for example in the case of an examination that includes more than 16 images).

12.3. Processing of the stored images

12.3.1. Listing

To display the listing of the archives:
From the acquisition screen, press the QuickButton; the **configuration menu** is displayed.

```
Exit
.
.
.
New Archive
Archives :    4 archives     32 images
```

In the **configuration menu**, the information displayed beside **Archives** indicates the number of archives and the number of stored images.

Put the cursor on Archives : X archives Y images and press the QuickButton to displayed data about these archives.

If there is no stored archives, the following message is displayed:

```
No Archive
```

If archives are stored in the **BASIC**, a detailed listing of all the archives is displayed:

```
Patient 1      Lower limbs     04/09/2001  15 :12
Patient 2      Upper limbs     12/05/2001   9 :56
Patient 3      Cervical        23/04/2001   4 :36
Patient 4      Miscellaneous   03/09/2001  19 :25
```

`Patient 1`	Archive name
`Upper limbs`	Name of the examination territory
`04/09/2001  15 :12`	Date and time of the creation of the archive

To display the menu that allows the archive processing, put the cursor on the selected archive and press the QuickButton.

12.3.2.Archive processing menu

```
Archive

      Name :            Patient 1
      Date :            04/09/2001
      Territory :       Upper limbs
      Images :           12

      View
      Clear Archive?
      Send Archive to WinAtys?
      Print Full Archive
      Exit
```

The upper part includes a description of the archive:
- Name.
- Date and time of the creation of the archive.
- Territory of the examination.
- Number of images in the archive.

The lower part includes the menu.

Archive menu: View (put the cursor on **View** and press the QuickButton).
The stored images are displayed chronologically turning the QuickButton.
Press "**Pedal**" to print out the displayed image or to send it to the WinAtys software.
To leave the archive display press:
- «**NUL**» to go back to the **configuration menu**.
- The QuickButton to go back to the archive processing menu.

Archive menu: Clear Archive (put the cursor on **Clear Archive** and press the QuickButton)
The following message is displayed: **Clear Archive? YES, NO.**
Put the cursor on **YES** or **NO** and press the QuickButton to validate.
If the answer is **YES**, all the images of the archive are cleared and consequently lost.

Archive menu: Send Archive to WinAtys (put the cursor on **Send Archive** and press the QuickButton)
The complete archive is sent through the RS232 connection to the PC fitted with the WinAtys software.
An empty examination will have been selected in the WinAtys software.
The Connection/Disconnection icon of WinAtys must be activated.

Archive menu: Print Full Archive (put the cursor on **Print Full Archive** and press the QuickButton)
Print all the images of the archive on the integrated thermal printer of the **BASIC**.

Menu archives: Exit (put the cursor on **Exit** and press the QuickButton)
Return to the **configuration menu**.

12.4. Storage capacity

The memory capacity is 120 images into 16 archives at most.

12.4.1.Archive full

When an archive is full (after the storage of the 16th image), the following message is displayed.

Archive FULL Archive closed Do you want: Open a new archive Continue without archiving

You can either open a new archive or continue without archive. Put the cursor on the selected option and press the QuickButton.

Continue without archiving: Allows to resume the examination without archiving.
Once the above message is displayed, press the QuickButton to continue without archiving.

Open new archive: Allows to open a new archive to continue the storage of the examination results.

12.5. Storage memory full

After the storage of the 120th image, the following message is displayed.

Archives FULL Do you want: Clear oldest archive Continue without archiving Ignore

You can either clear the oldest archive, continue without archiving or clear any archive. Put the cursor on the selected option and press the QuickButton.

Clear oldest archive: Allows to clear the oldest archive. All the pictures of this archive are then lost.

Continue without archiving: Allows to resume the examination without archiving.
Once the above message is displayed, press the QuickButton to continue without archiving.

Ignore: The memory is full but the user has then the possibility to clear any archive (not necessary the oldest one).

When there are 120 images in the memory, the following message is displayed as soon as the user tries to store a new (121st) image.

Archives FULL Do you want: Clear oldest archive Print

You can either clear the oldest archive or printout the display. Put the cursor on the selected option and press the QuickButton.

Clear oldest archive: Allows to clear the oldest archive. All the pictures of this archive are then lost.

Print: Allows to print out the display.

13. CONFIGURATION

The **configuration menu**s are used to:

- Select a vessel name.
- Select an examination.
- Define a probe or sensor configuration.
- Adjust the date and time.
- Define the unit configuration.
- Process archives (see § 12).

From the acquisition program, press the QuickButton to reach the **configuration menu**.

```
Exit
Side (left, right, or blank)
Select vessel
Examination (if not frozen)
Probe configuration
Date and Time
Unit configuration
New Archive(*)
Close Archive(*)
Archives :    4 archives     32 images
```

(*) These two lines are not displayed simultaneously.

13.1. Side

From the acquisition program pressing the QuickButton two times allows to change the displayed side. This is valid under the following condition: a side must have been selected in the "**Select vessel**" configuration panel.

13.2. Select vessel

It is possible to display the name of the studied vessel. This name can be selected in a list.

To select the name of the vessel, the following operations are to be performed:

- Press the QuickButton from the acquisition program to display the **configuration menu**.
- With the QuickButton select "**Select vessel**".
- Press the QuickButton to validate.
- The cursor is on the territory field. To modify the territory press the QuickButton. Turn the QuickButton to change the territory (lower limbs (Lowers), upper limbs (Uppers), miscellaneous, cervical, pressure in lower limb (Lowers W. Pressure), pressure in upper limb (Uppers W. Pressure)). Press the QuickButton to validate your choice.
- Turning the QuickButton, move the cursor to the side field. Press the QuickButton to validate. Turn the QuickButton to select the side. Press the QuickButton to validate.
- Turn the QuickButton to select the name of the vessel. Press the QuickButton to validate your choice.
- Once the vessel name is validated the "**Select vessel**" panel is left and the acquisition screen is displayed.

Press "**Null**" to exit the "**Select vessel**" panel without selecting a new vessel.

13.3. Examination

```
DOP.4M
DOP.8M
PPG Ph2
PPG Pn1
PPG Ph1
V.R.T
```

To select the type of the examination, the following operations are to be performed:

- Press the QuickButton from the acquisition screen to display the configuration panel.
- Turn the QuickButton to select "**Examination**" **(if not frozen)**.
- Press the QuickButton to validate.
- Turn the QuickButton to select the examination.
- Press the QuickButton to validate.
- Once the examination is validated, the menu is left and the acquisition screen is displayed.

Press "**Null**" to exit the menu without selecting a new vessel.

It is impossible to select a new examination if the acquisition is frozen.

13.4. Probe configuration

13.4.1.Introduction

For each probe or sensor, a **configuration menu** of the indices is available.
This **probe configuration** menu allows to attach different indices to each probe or sensor that can be used for distinct applications.

13.4.2.Display and printing configuration

Press the QuickButton from the acquisition screen to display the configuration panel.
Turn the QuickButton to select **Probe configuration**.
Press the QuickButton to validate.

This menu depends on the selected examination as indicated in the hereafter table.

Dop 4	Dop 8	PPG ph1 and ph2	PVR Pn1
4 MHz Exit Diameter 10 mm Angle 60dg INDEX-INDICES # Nr. Labl unit 1 15H.R. BPM 2 1SSys cm/s 3 7Aver cm/s 4 0	8 MHz Exit Diameter 10 mm Angle 60dg INDEX-INDICES # Nr. Labl unit 1 15H.R. BPM 2 1SSys cm/s 3 7Aver cm/s	Photo1 Exit Diameter *not used* Angle *not used* INDEX-INDICES # Nr. Labl unit 1 15H.R. BPM 2 12PlsL 3 13PlsR 4 0	Pneum Exit Diameter *not used* Angle *not used* INDEX-INDICES # Nr. Labl unit 1 15H.R. BPM 2 12PlsL 3 0 4 0

There is no configuration menu for the V.R.T.

13.4.3.Index configuration

Up to four indices can be displayed in real time. These indices are selected in the probe configuration menu.

Each index comprises a name and a unit.

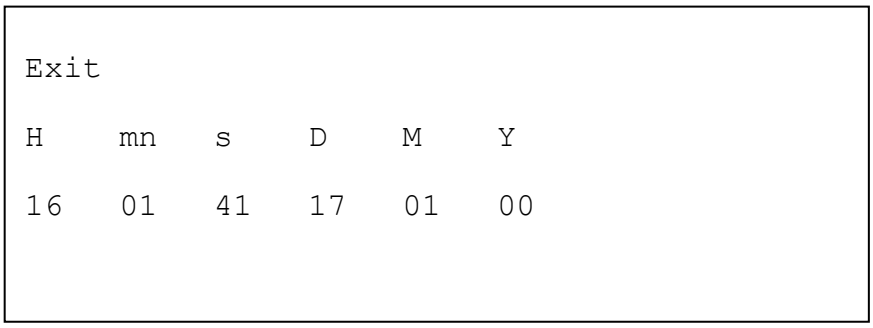
The following operations have to be done in order to change the index configuration of a probe or a sensor:

- Press the QuickButton from the acquisition program to display the configuration panel.
- Turning the QuickButton, select the probe configuration.
- Press the QuickButton to validate.
- The four indices are reported in the bottom of the panel. Turning the QuickButton to select with the cursor the index to be changed, press the QuickButton to validate.
- Use the QuickButton to change the number of the selected index.
- The name and the unit corresponding to the index number are displayed.
- Press the QuickButton to validate.
- Do all the necessary modifications.
- Press "**Null**" (or select "**Exit**" and press "**Enter**") to leave the probe configuration panel.
- The configuration is automatically stored.

13.4.4.Index list

Symbol	unit	Function
		No index displayed at this place
SysV	cm/s	Systolic Velocity
DiaV	cm/s	Diastolic Velocity
SysF	kHz	Systolic Frequency
DiaF	kHz	Diastolic Frequency
S/D		Systolic / Diatolic
RI		Resistance Index
PI		Pulsatility Index
PI.2		Pulsatility Index (2 decimal)
Aver	cm/s	Speed Average
H.R.	BPM	Heart Rate
Flow	l/min	Flow rate
Pres	mmHg	Pressure
PlsL		Plethysmo pulsatility Left
PlsR		Plethysmo pulsatility Right
Sym	%	Plethysmo symetry L/R
RPI		Resiudal Pressure Index
The following three indices are automatically displayed during the V.R.T.; they cannot be selected in the probe configuration menus.		
TO	s	Time Outflow
TH	s	Half Time Outflow
VO	%	Venous Outflow

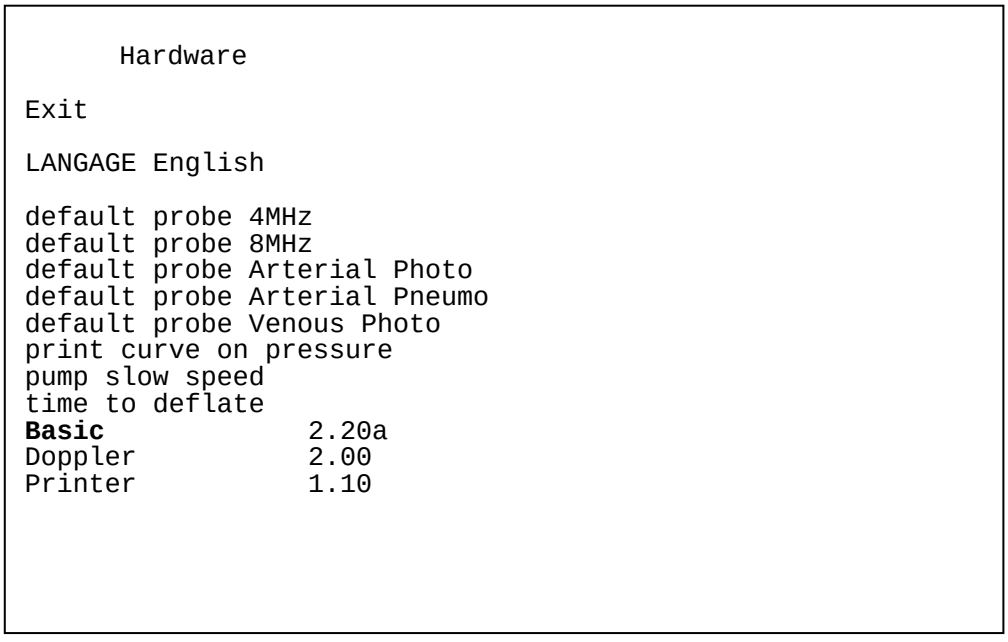
13.5. Date and time



To change the date and the time, the following operations are to be performed:

- From the acquisition screen, press the QuickButton. The configuration panel is then available.
- Select the "**Date and Time**" with the QuickButton.
- Press the QuickButton to validate.
- Select the data to be modified turning the QuickButton.
- Press the QuickButton to validate.
- Change the value of the units or of the tens turning the QuickButton.
  If the total value is not correct, it is necessary to modify the units before the tens and vice versa. For example, to change the time from 24 h to 15 h, first change 2 in 1 then 4 in 5 (25 h is not a correct time). To change the day number from 29 to 30, change first 9 in 0 then 2 in 3 (39 is not a correct day number).
- Press the QuickButton to validate.
- Press the "**Null**" key or select "**Exit**" and press the QuickButton to leave the date and time configuration panel.

13.6. Unit configuration



The unit configuration allows to choose the language, to adjust the pump speed, to input the deflating delay and to initialise each probe or sensor parameters to the default values.

To change language, the following operations are to be performed:
- From the acquisition screen, press the QuickButton. The configuration panel is then available.
- Select the "**Unit configuration**" with the QuickButton.
- Press the QuickButton to validate.
- Select **language** turning the QuickButton and press the QuickButton to validate.
- Adjust the language turning the QuickButton.
- Press the QuickButton to validate.
- Press the "**Null**" key or select "**Exit**" and press the QuickButton to leave the unit configuration panel.

To change the configuration of the printout of the pressure:
- From the acquisition program, press the QuickButton. The configuration panel is then available.
- Select the "**Unit configuration**" with the QuickButton.
- Press the QuickButton to validate.
- Select **Print curve on pressure** with the QuickButton and press the QuickButton to validate.
- Select 1 to print the curves with the pressure values. Select 0 to print the pressure values without the curves.
- Press the QuickButton to validate.
- Press the "**Null**" key or select "**Exit**" and press the QuickButton to leave the unit configuration panel.

To change the deflation delay, the following operations are to be performed:
The deflating delay is elapsed time between the end of the inflating (after the occlusion) and the start of the deflating.
- From the acquisition screen press the QuickButton.
- Select "**Unit configuration**" turning the QuickButton and press the QuickButton to validate.
- Select "**time to deflate**" with the QuickButton and press again the QuickButton.
- Adjust the deflation delay from 1 to 6 s turning the QuickButton.
- Press QuickButton to validate.
- Press the "**Null**" key or select "**Exit**" and press the QuickButton to leave the unit configuration panel.

To change the pump speed, the following operations are to be performed:
- From the acquisition screen, press the QuickButton. The configuration panel is then available.
- Select the "**Unit configuration**" with the QuickButton.
- Press **the** QuickButton to validate.
- Select "**pump slow speed**" turning the QuickButton and press the QuickButton.
- Adjust the pump speed with the QuickButton. The default value is 2.
- Press the QuickButton to validate.
- Press the "**Null**" key or select "**Exit**" and press the QuickButton to leave the unit configuration panel.

13.7. New archive

See section 12

13.8. Close archive

See section 12

13.9. Archive: X archives Y images

See section 12

14. SPECIFICATIONS

14.1. Continuous Doppler

True bi-directional Doppler for the sound and directional Doppler for the display.
Frequencies: 4 MHz or 8 MHz.
Ultrasonic power < 50 mW/cm².
Filters: Artery 1, Artery 2, Vein and Average.
Sign selection.
Zero line location: three locations available.

14.2. Pressure transducer

Accuracy: 0-300 mmHg ± 3 mmHg or 2 % of reading, whichever is greater.
40 bpm ≤ heart rate ≤ 180 bpm.

14.3. Printing

Paper width: 60 mm.
Resolution 200 DPI, 8 dots per mm.
Printing speed: up to 25 mm/s.
Paper roll length: 25 m.

14.4. Sound

Sound stereo amplifier: 2x 40 W RMS.
Volume control on the front side.
Headphone socket by Jack 3.5 mm.

14.5. Control

Membrane key board with 9 keys.
QuickButton.
Foot switch pedal for the printing control: single or dual in option

14.6. Display

Backlighted liquid crystal display: 120 mm * 64 mm.
Resolution: 2 dots/mm.
Control of the contrast on the front panel.

14.7. Environmental characteristics

Operating: 10 to 30 °C, 0-100 % Hr (no condensation).
Non operating: 10 to 50 °C, 0-100 % Hr (no condensation).

14.8. Electrical characteristics

110 VAC, +7 %, -13 %, 50-60 Hz.
220 VAC, +7 %, -13 %, 50-60 Hz.
Power and fuses: see indications on the appliance.

14.9. Mechanical characteristics

Dimensions:	Width = 28 cm Depth = 29 cm Height = 16 cm
Weight:	8.5 kg

14.10. Safety

BASIC is compliant with IEC 601-1 international code of safety.
Class 1 type BF appliance.

Mechanical protection index: IP20.

Water leaktightness height of the probes: 20 mm.

14.11. Regulation

CE 0459

BASIC is compliant with the following international code:
EN 55011 (CISPR11)
IEC 801-2,3,4,5.
BASIC is compliant with the CE mark EMC.
BASIC is designed and manufacture with the **ISO9001/EN46001** quality system.

15. CLINICAL SAFETY OF ULTRASOUND AND THE ALARA PRINCIPLE

The American Institute of Ultrasound in Medicine has addressed the issue of the safety of ultrasound. The Institute issued the following statement concerning the clinical safety of ultrasound as of October 1983:

"Diagnostic ultrasound has been in use for 25 years. Given its known benefits and recognised efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicates that the benefits to patients of the prudent use of diagnostic ultrasound outweighs the risks, if any, that may be present."

The exposure at ultrasound should always be limited to As Low As Reasonably Achievable (ALARA principle).
You can control the exposure to ultrasound by limiting the duration of the exposure.
Atys has always endeavoured to use as low an ultrasonic power output for our products as is practical. All power levels are significantly below those currently established by the FDA as limits above which specific review is necessary.

Ultrasound power output measurements
Power measurements, acoustic measurements and mathematical calculations were carried out by TIMUG, EV, Villiper Allee 8, D-53125 Bonn, GERMANY. A test report is available.

Measurements for the calculation of spatial peak temporal average intensity, I_{SPTA} were carried out using calibrated PCDF hydrophone probes following the instructions and standards of the American Institute of Ultrasound in Medicine (AIUM). For the report, three measurements are made, here one measurement is provided.

Parameters	4 MHz	8 MHz
$I_{SPTA.3}$ (Max value)	167	346
Power (mW)	14.7	18.3
fo (MHz)	4.1	8.2
Z_{sp} (cm)	0.98	0.67
$X_{-6}Y_{-6}$	0.24, 020	0.23, 0.09
Az (cm)	0.8	0.6
Ele (cm)	0.4	0.3

Glossary of terms
$I_{SPTA.3}$: Derated spatial peak temporal average intensity (mW/cm^2).
Power : ultrasonic power (mW).
fo : Centre frequency (MHz).
Z_{sp} : Axial distance used to calculate the derated intensity (cm).
$X_{-6}Y_{-6}$: Respectively the in-plane (azimutal) and out of plane (elevational) –6 dB dimensions in the x-y plane where Z_{sp} is found (cm).
Az : Entrance beam dimensions for the azimutal plane (cm^2).
Ele : Entrance beam dimensions for the elevational plane (cm^2).

The derated intensity calculations are based on the measured center frequency of the acoustic signal (f MHz) and the distance from the transducer under test to the hydrophone (d cm) using the derating factor $e^{-0.069*f*d}$

Acoustic measurement uncertainties
The uncertainties in the measurements were predominantly systematic in origin. The total uncertainties below ± 20 % is given for all the intensities values reported.

16. CLINICAL ACCURACY

16.1. Doppler

The subject devices allow to measure the Doppler shift and consequently the blood velocity in vessels.
4 and 8 MHz transducers allow to measure the real time blood velocity of blood in peripheral arteries and veins.

16.1.1.Accuracy of the measurement

The clinical accuracy measurements of the velocity were carried out by APAVE, 177, route de Sain-Bel, 69 811 TASSIN CEDEX, FRANCE (file N° CNH 95 / 8262).
The measurements were carried out with a string phantom: SS 2A Instruments, MARK 4.
Four constant velocities (25, 50, 100, 200 cm/s) were measured in water at a 60° angle with forward and backward flow, for each frequency and for each filter. Since the calculation of the velocity is for an insonation angle of 0°, the values were corrected using the cosine of the actual angle of measurement.
The accuracy values are listed in the table below. The accuracy is given with regards to the constant speed.

Frequency	Constant speed (cm/s)			
	25	50	100	200
4 MHz CW	<5%	<2%	<1%	<2.5%
8 MHz CW	<4%	<2%	<1%	<2.5%

As can be seen, the accuracy is high over the whole range of velocities.

16.1.2.Range of Doppler controls

Doppler Phantom		
Frequency	Min Velocity (cm/s)	Max Velocity (cm/s)
4 MHz	10	100
8 MHz	10	100

Doppler Sensitivity				
Min frequency (Hz)	Min velocity at 60° (cm/s)	Max frequency (kHz)	Max displayed velocity on the waveform (cm/s)	Max displayed velocity as an index (cm/s)
200	8	6.0	192	240
200	4	12.0	192	240

The velocity is calculated on the selected frequency.
The velocity is displayed on the scale. The scale is adjustable as 5 cm/s/div, 10 cm/s/div, 20 cm/s/div and 40 cm/s/div.
The sweep velocity is adjustable as: 5 s/div, 1.6 s/div, 0.8 s/div, 0.4 s/div (1 div = 1 division = 1cm on the paper and 0.94 cm on the screen).

16.2. Photo-sensors

The arterial photo sensors are non focused sensors with two emitters and a centre receiver. Emission power is 13 mW typ. Emission intensity is from 1.7 mW/sr to 3.4 mW/sr *3 units.
The venous photo sensors are non focused sensors with four emitters and a centre receiver. Emission power is 13 mW typ. Emission intensity is from 1.7 mW/sr to 3.4 mW/sr *3 units. Receiver polarisation is adjusted for each unit to ensure the dynamic range.
S/N ratio is limited to the numeric conversion noise 42 dB. The total dynamic range is available using the on board adjustable gain.

16.3. Pneumo module

The pressure sensor is used to measure pressure level relative to atmospheric pressure level. Available range is from 0 to 300 mmHg. Sensor interface is adjusted in offset at +/-5 mbar and in

value at +/-5%. The sensor is soldered on the measurement/main board; so the board is calibrated for each production unit. S/N ratio is limited to the numeric conversion noise: 42 dB. The total dynamic range is available using the on-board adjustable gain.

17. CLEANING, DISINFECTION AND STERILISATION OF ATYS EQUIPMENT

The **BASIC** is not intended to be used on no-intact skin. It is a non critical patient contact device.

17.1. Doppler probes

This procedure concerns the 4 MHz and 8 MHz continuous pencil probes.

- Be very careful for the cleaning and disinfection of the probes.
- The tip of the probes may be damaged by shocks; the probes must be handled carefully.
- Never bend or pull the transducer cable.

The probe comes in contact with intact skin. So the risk of infection is low. The probe needs only be cleaned and low level disinfected between patients.

The use of a liquid low level disinfecting agent is recommended (for example: ethanol, iso alcohol).

Only FDA cleared cleaning agents must be used. The user must refer to the labeling instructions provided by the manufacturer of the cleaning agents.
Only FDA cleared low level disinfectant agents must be used. The user must refer to the labeling instructions provided by the manufacturer of the low level disinfecting agents.

Note: No components are supplied sterile to the user.

CAUTION: DO NOT USE THE FOLLOWING METHODS OF STERILISATION AND DISINFECTION. THEY WOULD INDUCE DAMAGES OF THE PROBES:

STERILISATION	**DISINFECTION**
AUTOCLAVE	CHLORINE 100 %
ULTRASOUND	GLUTARALDEHYDE AT 100 %
	HYDROGEN PEROXIDE 100 %
	IODINE AT 100 %

Long accumulation of ultrasound gel on the face of the probe will cause early degeneration and loss of performance. Always remove the coupling gel from the probes after each test.

Inspect probe regularly for visible cracks and leaks. If such damage is found do not use the probe. Your dealer will advice you if the probe can be repaired.

17.1.1.Periodical inspection

Perform an examination of the probe before use and just after each disinfection or sterilisation for visible cracks and leaks. If such damage is found do not use the probe. Your dealer will advice you if the probe can be repaired.

17.1.2.Precautions of storage

To prevent the probe damage, the probe must not be bent and wound tightly.

17.1.3.Reuse life

Perform an examination of the probe before use and just after each disinfection for visible cracks and leaks. If such damage is found do not use the probe. Your dealer will advice you if the probe can be repaired.
Before the use of the probe, when the probe is just connected to the machine, check the sound level. If the sound level is high, it means that the probe is damaged. So do not use the probe. Your dealer will advice you if the probe can be repaired.

17.2. Photo-plethysmography sensors

The sensors come in contact with intact skin. The risk of infection is low; so the sensors need only be cleaned and low level disinfected between patients.

Only FDA cleared cleaning agents must be used. The user must refer to the labeling instructions provided by the manufacturer of the cleaning agents.
Only FDA cleared low level disinfectant agents must be used. The user must refer to the labeling instructions provided by the manufacturer of the low level disinfecting agents.

The use of a liquid low level disinfecting agent is recommended (for example: ethanol, iso alcohol).

Note: No components are supplied sterile to the user.

17.3. Cuffs

Never place the cuffs over open wounds or allow them to come in contact with body fluid.
Use only hospital approved cleaning agents (FDA cleared) to clean the cuff **after** each use and wipe dry immediately (see the labeling from the cuff manufacture).

17.4. Console

- Always turn off the system and disconnect it from the power outlet before cleaning the machine. Otherwise, electric chock may result.
- Do not place fluid on or near the system.
- Clean the external surface (casing) with soft cloth soaked with alcohol.
- Make sure that the cloth is damp but not saturated, as you should avoid introducing fluids into areas of electrical components.
- The glass surfaces (screens, LCD,...) must be carefully cleaned in order to prevent to scratch them. Use optical lens cleaners to clean the glass surface.
- Allow the unit to dry before returning it to operation.

17.5. Screen

The screen is protected by synthetic pane against knocks.
Yet, cautions must be adopted at the cleaning of the pane not to damage it.
Cleaning with optical lens cleaners.

Caution: the screen must not be exposed at the sun or heat.

17.6. After sales service

To obtain additional information contact: your ATYS representative.

18. PACKING THE BASIC FOR SHIPPING

ATYS ships the system in a box specially designed for the **BASIC**. This box is made in wood and cardboard. This box includes foam guards for protecting the system. It is essential to ship the equipment using the original packing materials.

CAUTION: if you do not have the original packing materials, contact your ATYS dealer.

19. WASTING OF THE PACKAGE AND OF THE BASIC

The package and the **BASIC** do not contain any dangerous components.
The wasting of the package and the **BASIC** must be performed according the national regulations.

CAUTION: Before wasting the **BASIC**, it is necessary to remove the lithium button battery. The lithium battery is located on the main board (BPMIC). The lower cover must be removed to reach the BPMIC board. See the service manual for information about how to remove this cover.

20. CHARACTERISTICS OF THE PRESSURE CUFFS

The characteristics of the cuffs are reported hereafter.

- The cuffs include a cover, a bladder, a pipe and velcro or hook.
- The cuffs must be pressure cuffs.
- They are standard cuffs for vascular studies.
- The size of the cuffs must be well adjusted to the size if the limb or digit under study (arm, thigh or digit).
- The maximum internal pressure in the cuffs is 320 mmHg. The cuffs must be able to withstand this pressure.
- The cuffs are one tube model.
- The cuffs are washable.
- The cuffs are Velcro or hook cuff.

It is advised to use blood pressure cuffs from Welch Allyn or Hokanson. The cuffs must be FDA cleared.

21. UNDERSTANDING THE EXAMINATION RESULTS

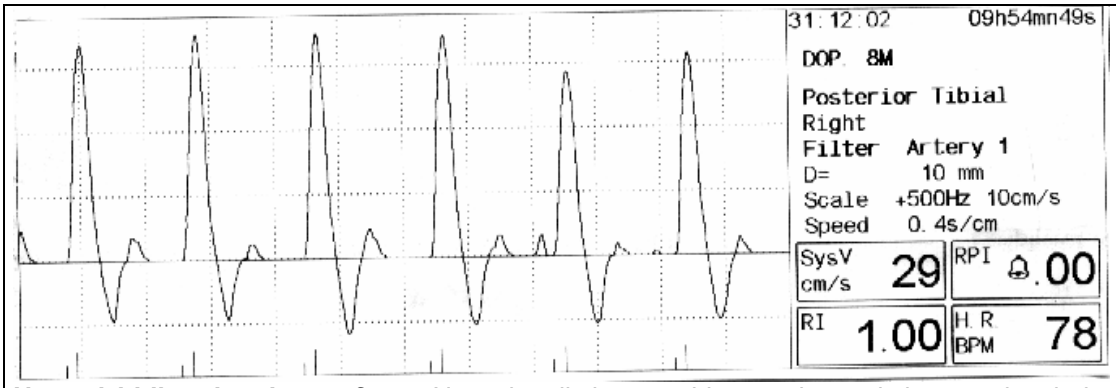
21.1. Arterial Doppler

One of the major methods of deriving diagnosis information from the Doppler is through examination of the recorder waveform (morphology). The four characteristics to be examined are:

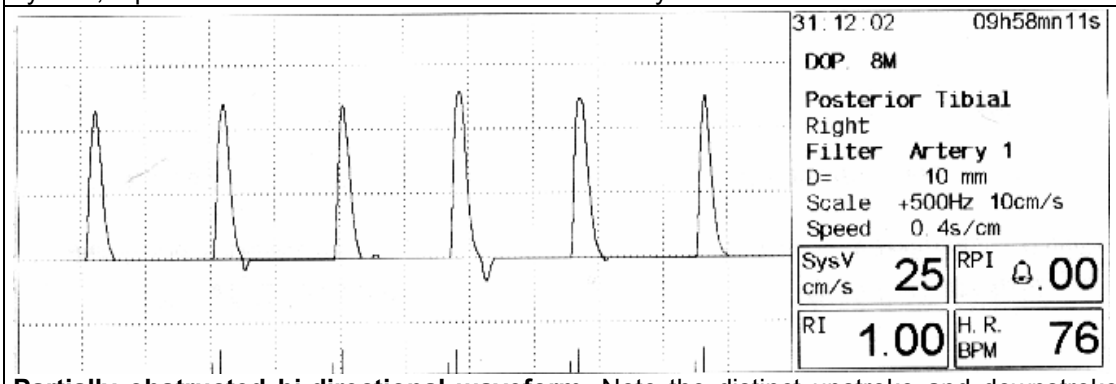
- Pulsatility
- Systolic forward flow
- Diastolic reverse flow
- Diastolic oscillations

Right and left side waveform recordings are analysed and compared.

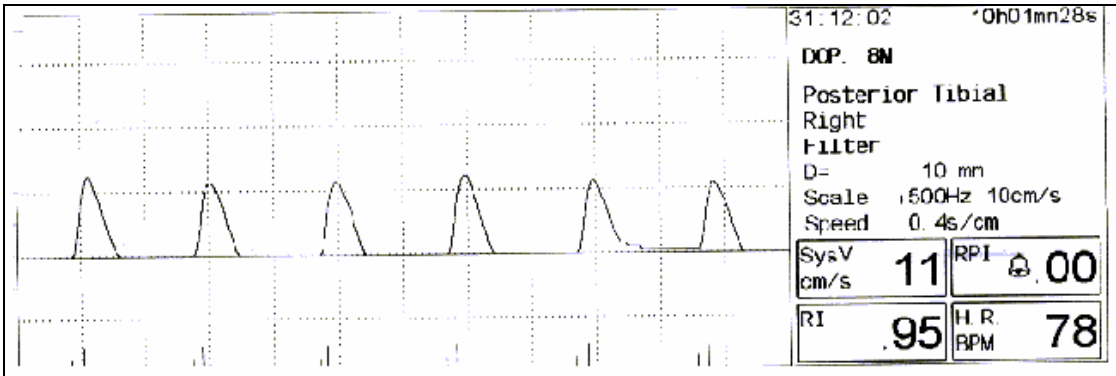
Waveform morphology may appear as follows.
The normal peripheral arterial Doppler waveform may exhibit multi-phasic pulsatility, sharp rapid systolic upstroke (A) and downstroke (B), and variable diastolic reverse flow (C) and oscillations depending on the artery from which the recording was taken.



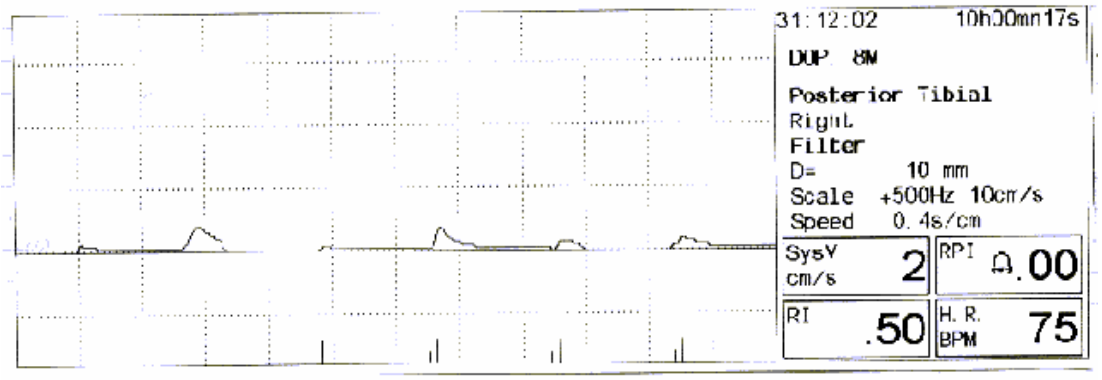
Normal bidirectional waveform. Note the distinct, rapid upstroke and downstroke during systole; rapid flow reversal and increase in flow velocity due to arterial wall elastic rebound.



Partially obstructed bi-directional waveform. Note the distinct upstroke and downstroke systole but diminished waveform height; partial loss of the flow reversal; and loss of the arterial wall's elastic rebound peak.



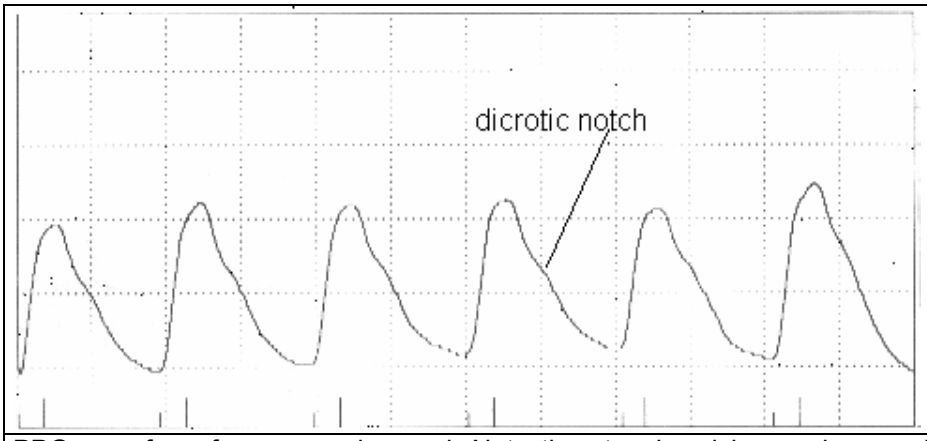
Increasingly obstructed bidirectional waveform. Note the rounding of the upstroke and downstroke during systole and diminished peak height; complete loss of the flow reversal; and complete loss of the arterial wall's elastic rebound.



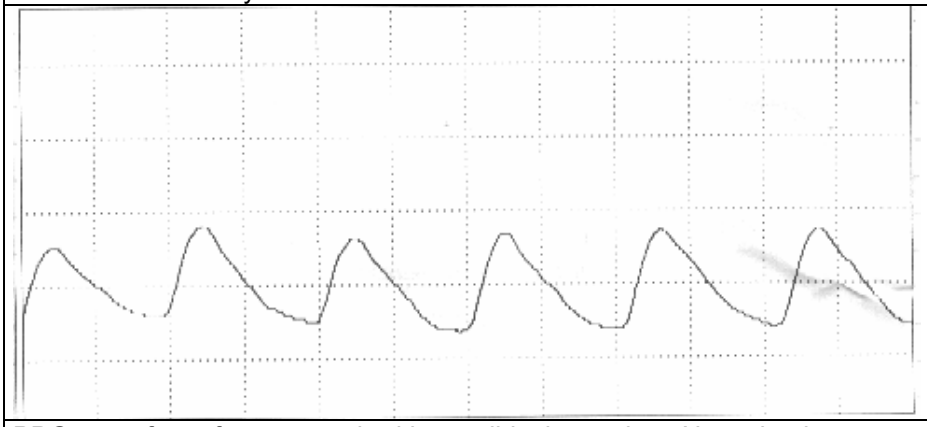
Severely obstructed bidirectional waveform. Note the dramatic loss of peak height during systole.

21.2. Arterial photoplethysmography

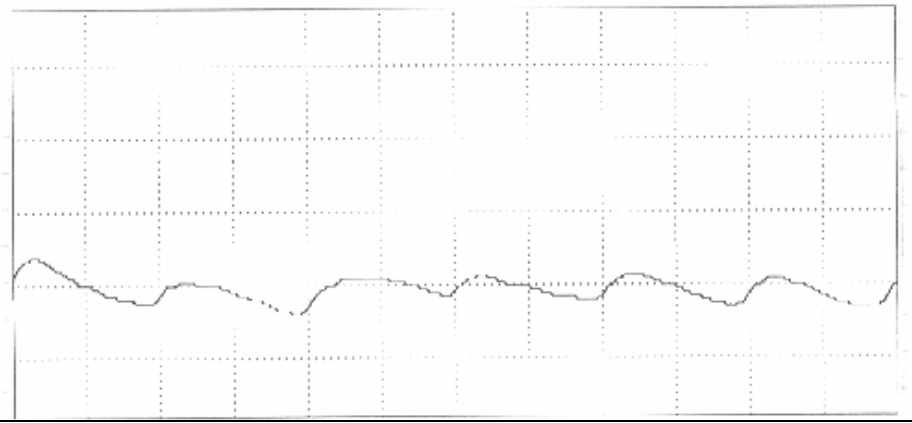
The following series of PPG waveforms range from the normal to the severely obstructed vessel. The illustrations show the steady deterioration of waveform features as the obstruction progresses.



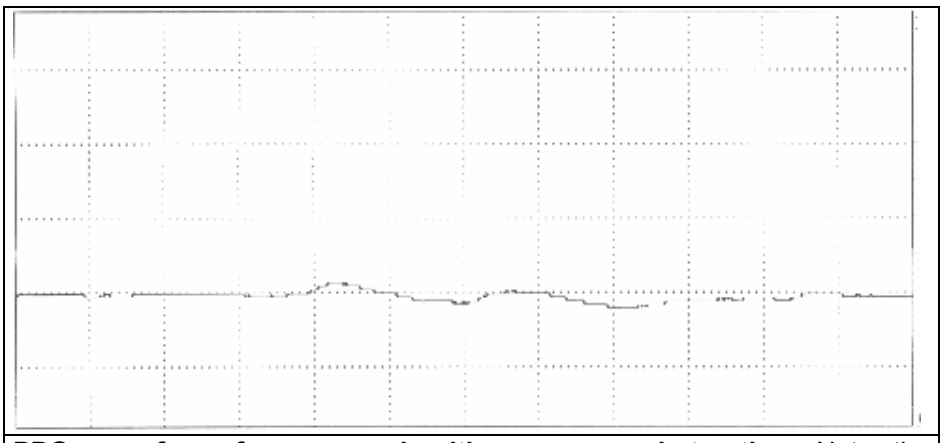
PPG waveform for a normal vessel. Note the steeply raising upslope and sharp peak during systole and distinct dicrotic notch indicating period of flow reversal in the artery.



PPG waveform for a vessel with a mild obstruction. Note the less steep upslope and a less distinct peak and loss of the dicrotic notch on the downslope.



PPG waveform for a vessel with a moderate obstruction. Note the low amplitude and marked abnormalities as in moderate obstruction..

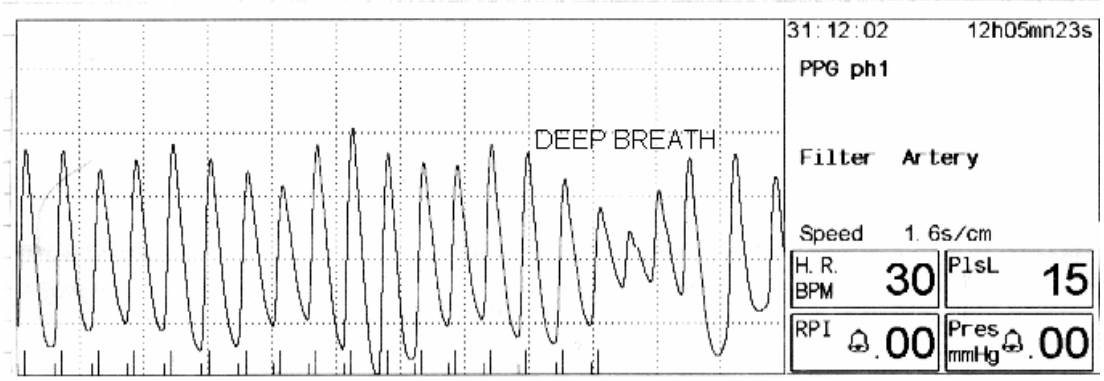


PPG waveform for a vessel with a severe obstruction. Note the disappearance of pulsations.

To test for sympathetic tone:

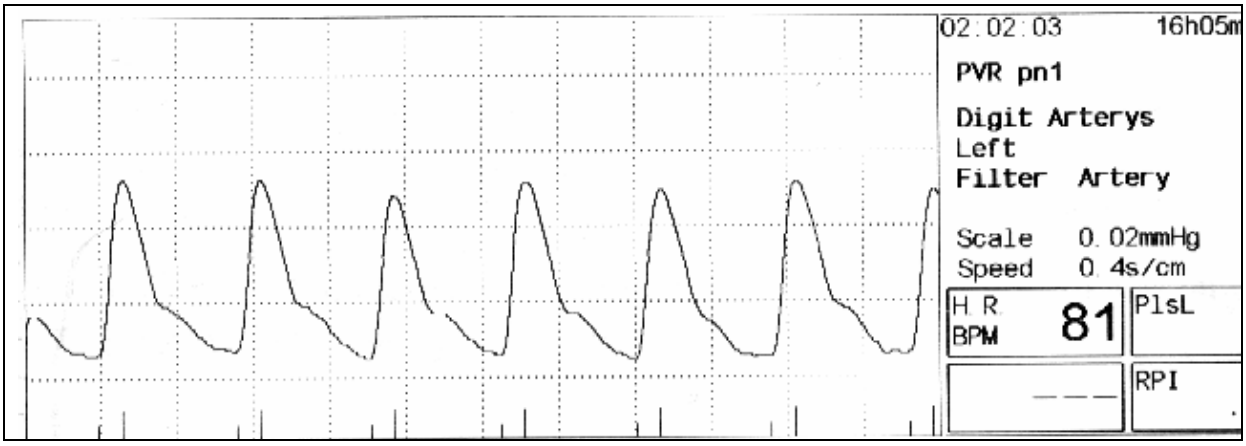
- The sweep speed was decreased to 1.6s/cm.
- Have the patient take and hold a deep breath, then release it.

The waveform pattern looks like this for a normal sympathetic response.



21.3. Air pneumoplethysmography - Pulse volume recording

The following illustration shows a normal waveform.



The deterioration of waveforms as the obstruction progresses is similar the one relative to photoplethysmography (see § 21.2).

21.4. Understanding the ABI test

You can use the following diagnostic guidelines (based on Buchbinder and Flanigan, "Arteril Disease of the Lower Extremities") for interpreting the index:

Condition	ABI
Normal	Above 0.96
Mild obstruction	0.71 – 0.96
Moderate obstruction	0.31 – 0.70
Sever obstruction	00 – 0.30

21.5. Understanding the segmental pressure test

The following criteria indicate that further examination is necessary:

- The upper thigh pressure should be 10 mmHg greater than the Brachial pressure. If it is less, it may indicate an obstruction.
- Pressure difference between adjacent cuff sites on the same leg (such as the lower thigh and calf) that exceed 20-30 mmHg may indicate an obstruction. Also pressure differences between cuff sites at the same level on opposite legs that exceed 20 mmHg may indicate an obstruction.
- A pressure difference of over 30 mmHg over the entire leg (from the upper thigh to the ankle) may indicate an obstruction.

The examination of the waveforms recorded during a segmental PVR (Pulse Volume Recording test) is useful to confirm the results of the segmental pressure test.

If the patient is symptomatic but the pressures appear to be normal, you may want to exercise the patient.

21.6. Understanding the digital test

The digital test is used to evaluate and characterise the arterial blood flow in hands and feet.
This exam can use:

- Doppler recording
- PPG waveforms recording
- Systolic pressure measurement
- Pulse volume measurement

Examine the waveforms (see § 21.1, 21.221.2, 21.3). Rounded and low height waveforms may indicate a possible obstruction.

You can also examine the RPI indices in the finger and toe.
RPI for finger = Finger systolic pressure/Highest brachial pressure.
RPI for toe = Toe systolic pressure/Highest brachial pressure.

You can use the following diagnostic guideline for interpreting the indices (based on Rutherford's Vascular Surgery):

Condition	RPI
Normal RPI for finger	0.75 or higher
Normal RPI for toe	0.75 or higher

21.7. Understanding the Venous Reflux Test (V.R.T.)

You can use the following guideline to interpret the results of the V.R.T.:

V.R.T. without tourniquet	
Normal	Refill time is greater than or equal to 20 s, indicating that the valves appear to be competent and that the arterial system begins to refill the venous system as the blood is forced out of the leg.
Abnormal	Refill time is less than 20 s indicating that the valves may be incompetent and the blood pumped out during reflux is allowed to flow backwards during the resting phase.
V.R.T. with tourniquet	
Normal	The deep veins appear to be competent but the superficial veins appear to be incompetent.
Abnormal	The deep veins appear to be incompetent and the superficial veins may or may not be incompetent.

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